

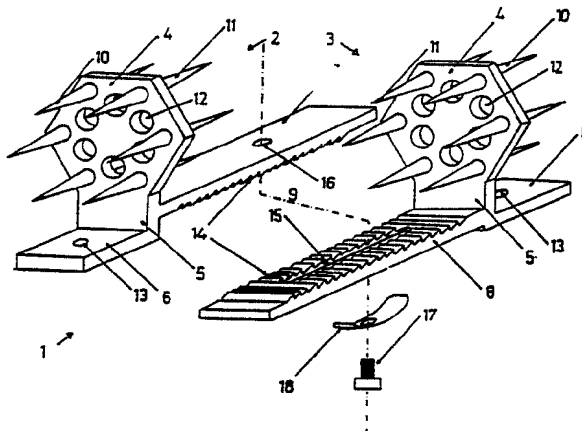
(51) Internationale Patentklassifikation 5 : A61F 2/44, A61B 17/60	A1	(11) Internationale Veröffentlichungsnummer: WO 92/01428 (43) Internationales Veröffentlichungsdatum: 6. Februar 1992 (06.02.92)
(21) Internationales Aktenzeichen: PCT/AT91/00090 (22) Internationales Anmeldedatum: 24. Juli 1991 (24.07.91) (30) Prioritätsdaten: A 1557/90 24. Juli 1990 (24.07.90) AT (71)(72) Anmelder und Erfinder: RASHEED, Mohamed, Ibrahim [EG/AT]; Klagergasse 5-7/2/17, A-1210 Wien (AT). (74) Anwälte: SONN, Helmut usw. ; Riemergasse 14, A-1010 Wien (AT). (81) Bestimmungsstaaten: AT, AT (europäisches Patent), AU, BB, BE (europäisches Patent), BF (OAPI Patent), BG, BJ (OAPI Patent), BR, CA, CF (OAPI Patent), CG (OAPI Patent), CH, CH (europäisches Patent), CI (OAPI Patent), CM (OAPI Patent), CS, DE, DE (europäisches Patent), DK, DK (europäisches Patent), ES, ES (europäisches Patent), FI, FR (europäisches Patent), GA (OAPI Patent), GB, GB (europäisches Patent), GN (OAPI Patent), GR (europäisches Patent), HU, IT (europäisches Patent), JP, KP, KR, LK, LU, LU (europäisches Patent), MC, MG, ML (OAPI Patent), MN, MR (OAPI Patent), MW, NL, NL (europäisches Patent), NO, PL, RO, SD, + SE, SE (europäisches Patent), SN (OAPI Patent), SU, TD (OAPI Patent), TG (OAPI Patent), US.		Veröffentlicht <i>Mit internationalem Recherchenbericht.</i>

(54) Title: ARTIFICIAL VERTEBRA

(54) Bezeichnung: WIRBELPROTHESE

(57) Abstract

Described is an artificial vertebra designed to be implanted in place of one or more damaged vertebrae, the artificial vertebra having two bracket plates designed to rest against the ends of the neighbouring stable vertebrae. The bracket plates have spikes for anchoring them in these neighbouring vertebrae and are connected to each other by a brace whose length can be adjusted. The brace (9) is disposed out of the longitudinal axis of the artificial vertebra (1), as defined by the line joining the mid-points of the two bracket plates (4). The brace (9) has two flat bars (7, 8) with, on the two facing sides, rows of teeth (14) which engage with each other, the bars (7, 8) being joined to each other by a bolt (17). An empty space is left between the bracket plates (4) to hold an implant (32) made of natural and/or synthetic material. Also described is a device for handling the artificial vertebra, in particular for inserting it.



(57) Zusammenfassung

Gezeigt wird eine Wirbelprothese zum Einsetzen anstelle eines oder mehrerer zerstörter Wirbelkörper mit zwei Stützplatten zur Anlage an den Stirnflächen benachbarter stabiler Wirbelkörper, wobei die Stützplatten Dorne zur Verankerung in diesen benachbarten Wirbelkörpern aufweisen und durch einen in der Länge verstellbaren Abstandhalter verbunden sind, wobei der Abstandhalter (9) außermittig bezüglich der durch die Mittelpunkte der Stützplatten (4) definierten Längsachse der Wirbelprothese (1) angeordnet ist und zwei Schienen (7, 8) mit an den einander zugewandten Seiten ineinander eingreifenden Zähnen (14) aufweist, wobei die Schienen (7, 8) mittels einer Schraube (17) miteinander verbunden sind und zwischen den Stützplatten (4) ein freier Aufnahmeraum zur Aufnahme eines Implantats (32) aus natürlichem und/oder künstlichem Material belassen ist. Weiters wird eine Vorrichtung zur Handhabung dieser Wirbelprothese, insbesondere zum Einsetzen derselben, gezeigt.

+ BENENNUNGEN VON "SU"

Es ist noch nicht bekannt, für welche Staaten der früheren Sowjetunion eine Benennung der Sowjetunion gilt.

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Wirbelprothese

Die vorliegende Erfindung betrifft eine Wirbelprothese zum Einsetzen anstelle eines oder mehrerer zerstörter Wirbelkörper, mit zwei Stützplatten zur Anlage an den Stirnflächen benachbarter stabiler Wirbelkörper, wobei die Stützplatten Verankerungsmittel zur Verankerung in diesen Wirbelkörpern aufweisen und durch mindestens einen in der Länge verstellbaren Abstandhalter verbunden sind.

Weiters bezieht sich die Erfindung auf eine Vorrichtung zur Handhabung dieser Wirbelprothese.

Wenn ein oder mehrere kranke oder zerstörte Wirbelkörper aus der Wirbelsäule entfernt werden müssen, sei es, daß die Wirbelkörper von Metastasen befallen sind, sei es wegen epiduraler Wirbelkanalmetastasen oder wegen funktioneller Instabilität der Wirbelsäule, war es bisher erforderlich, die kranken oder zerstörten Wirbelkörper zur Gänze aus der Wirbelsäule zu entfernen und eine Prothese zwischen den verbleibenden gesunden Wirbelkörpern der Wirbelsäule einzusetzen.

Zur Längenanpassung wurden beispielsweise Wirbelprothesen, bzw. Teile der Wirbelprothesen, mit verschiedenen festen Längenabmessungen benutzt, wobei die Anpassung an den zu überbrückenden Abstand während der Operation durch Abmessen der Lücke zwischen den verbliebenen gesunden Wirbelkörpern und Auswahl der geeigneten Prothese bzw. eines geeigneten Zwischenteils, mit Zusammenbau der Prothese während der Operation, erfolgt. Eine mehrteilige Prothese mit verschieden langen Zwischenstücken ist beispielsweise in der US-PS 4 599 086 beschrieben. Ein Nachteil dieser bekannten Prothese liegt in ihrem komplizierten Aufbau aus vielen Teilen und der umständlichen Manipulation beim Einsetzen. Die EP-PS 0 179 695 und die DE-OS 2 365 873 beschreiben ähnliche Wirbelprothesen mit fester Länge.

Andererseits kann die Wirbelprothese während der Operation individuell gefertigt werden, wie im Falle des in der DD-PS 235 416 beschriebenen alloplastischen Wirbelkörperersatzes. Nachteilig daran ist jedoch, daß dieser Wirbelkörperersatz nur mit einer Schraube und einem Drahtstift in den angrenzenden gesunden Wirbelkörpern verankert ist. Der in der EP-A 0 268 115 gezeigte, ebenfalls während der Operation individuell gefertigte zylinderförmige Blechmantel mit Durchbrechungen in der Mantelwand, der

mit Knochenstücken und/oder Knochenzement gefüllt wird, hat den Nachteil, daß der Knochenzement bei der Aushärtung lokal Temperaturen erreicht, die zu Nekrosen des umliegenden Gewebes führen können.

Darüberhinaus sind auch Wirbelprothesen bekannt, die in ihrer Länge durch verschiedene Mittel verstellbar sind. In ihrer Länge verstellbare Wirbelprothesen sind in der US-PS 4 657 550, US-PS 4 553 273 und DE-OS 37 29 600 beschrieben. Dabei handelt es sich immer um Anordnungen, in denen der Abstand zwischen zwei Stützkörpern mittels eines mittigen Spindeltriebes verstellbar ist. Die in der US-PS 4 553 273 beschriebenen blockförmigen Stützkörper, an denen sich der Spindeltrieb abstützt, sind in den jeweils angrenzenden Wirbelkörpern zu schaffenden, vorzugsweise polygonalen Ausnehmungen versenkt. Ein Nachteil hiervon ist daher auch, daß die Ausnehmungen während der Operation geschaffen werden müssen, was ein zeitraubendes und kompliziertes Verfahren nötig macht. Die Ausnehmungen müssen genau nach den Maßen der Stützkörper in die angrenzenden Wirbelkörper geschnitten werden, da ansonsten keine sichere Befestigung gegeben ist. Die in der DE-OS 37 29 600 beschriebenen winkelförmigen Stützkörper werden ohne Befestigung an den Stirnflächen der Wirbelkörper mit diesen nur seitlich durch Knochenschrauben verschraubt. Eine andere Möglichkeit der Befestigung der Stützkörper ist in der US-PS 4 657 550 beschrieben, nämlich die Verankerung durch Dorne in den angrenzenden Wirbelkörpern. Allen diesen Ausbildungen gemeinsam ist jedoch der Nachteil, daß bei Vorsehen eines mittigen längenverstellbaren Abstandhalters kein Implantat verwendet werden kann.

Weiters beschreibt die DE-A1 30 23 942 ein Distanzstück für den prothetischen Wirbelkörperersatz und ein Werkzeug zum Einsetzen desselben. Auch hier kann kein Implantat verwendet werden und das Werkzeug besteht aus einer zangenartigen Vorrichtung mit speziell ausgebildeten Zangenschenkel und einer Rasteinrichtung zum Festhalten seiner Spreizstellung.

Eine Aufgabe der vorliegenden Erfindung ist es nun, eine der Länge nach leicht verstellbare Wirbelprothese zu schaffen, die die Nachteile der oben genannten bekannten Wirbelprothesen nicht aufweist, sondern mittig ein Implantat aufnehmen und gegebenenfalls fixieren kann, und durch welche auch nur Teile von zerstörten Wirbelkörpern ersetzt werden können, d.h. daß nicht

immer der ganze Wirbelkörper entfernt werden muß, auch wenn er nur teilweise stark beschädigt ist. Daher sind, wenn hier von "benachbarten Wirbelkörpern" die Rede ist, damit auch die verbliebenen stabilen Teile von teilweise entfernten Wirbelkörpern gemeint. Weiters sind unter "stabile Wirbelkörper(teilen)" solche Wirbelkörper bzw. Wirbelkörperteile zu verstehen, die nach Ansicht des Chirurgen dazu imstande sind, der eingesetzten Prothese ausreichenden Halt zu gewähren.

Diese Aufgabe wird erfindungsgemäß dadurch gelöst, daß der Abstandhalter außermittig bezüglich der durch die Mittelpunkt der Stützplatten definierten Längsachse der Wirbelprothese angeordnet ist, wobei zwischen den Stützplatten ein freier Aufnahmeraum zur Aufnahme eines Implantats aus natürlichem und/oder künstlichem Material belassen ist. Die außermittige Anordnung des Abstandhalters ermöglicht es, bei einer stabilen, auf verschiedene Längen einstellbaren Prothese ein Implantat einzufügen. Die Prothesenkonstruktion kann dadurch erheblich entlastet werden, da das Implantat auch einen beträchtlichen Teil des auf der Wirbelsäule lastenden Druckes aufnehmen kann. Selbstverständlich kann jedes geeignete künstliche Ersatzstück das Implantat bilden. Bevorzugt wird aber ein natürliches, am Besten aus körpereigenen Knochen entnommenes Knochenimplantat oder ein aus Knochenteilen und Knochenzement hergestelltes. Jedenfalls kann dann mit der vorliegenden Erfindung die Menge des in den Körper des Patienten einzusetzenden gewebefremden Materials auf ein Minimum beschränkt werden.

Günstig ist, wenn die Verankerungsmittel Dorne sind. Diese dringen dann nach dem Einsetzen der Wirbelprothese und Aufheben der bei der Operation nötigen Streckung der Wirbelsäule des Patienten von selbst in die benachbarten Wirbelkörper ein.

Die bevorzugte Anwendung einer Stützplatte mit mindestens einer Durchbrechung ermöglicht bei Verwendung eines Knochenimplantats das natürliche Zusammenwachsen von Knochenmaterial innerhalb der Wirbelsäule durch die Stützplatten hindurch. Sind mehrere solcher Durchbrechungen vorhanden, ergibt sich ein besonders gefestigter Halt der Prothese nach dem Verwachsen. Zusätzlich sichert dies auch die Möglichkeit der nur teilweisen Entfernung von Wirbelkörpern und die sichere Verbindung mit den verbleibenden stabilen Wirbelkörperteilen.

Dabei ist es weiters günstig, wenn die Durchbrechungen kreisrund ausgebildet sind, da dadurch die Herstellung derselben erleichtert wird.

Gemäß einer bevorzugten Ausführungsform der Erfindung ist vorgesehen, daß in ungefährrer Fortsetzung des außermittigen Abstandhalters Anschlußstücke, die mindestens eine Durchbrechung für eine in den angrenzenden Wirbelkörper seitlich eindringende Knochenschraube aufweisen, mit den Stützplatten verbunden sind. Die Knochenschraube kann dabei so lang gewählt werden, daß sie bis in den Wirbelbogen des betreffenden Wirbelkörpers reicht. Dadurch ist zusätzlich zu den in den stabilen Wirbelkörper eindringenden Dornen eine sichere Fixierung gegeben. Es wird auch noch leicht ermöglicht, einen kranken oder zerstörten Wirbelkörper nur teilweise zu entfernen. Bei Verwendung einer langen Knochenschraube müssen die zur Verankerung in den angrenzenden Wirbelkörpern vorgesehenen Dorne selbstverständlich derart angeordnet sein, daß die Knochenschraube zwischen diesen hindurchgeschraubt werden kann. Daß diese Anschlußstücke in ungefährrer Fortsetzung des Abstandhalters liegen ermöglicht es auch die Wunde so gering wie möglich zu halten, weil dann der Zugang zu den Schrauben der Anschlußstücke und zum Verstellmechanismus des Abstandhalters von der gleichen Seite her und nur etwas höhenversetzt erfolgt.

Die Verwendung von Anschlußstücken bei der Konstruktion von Wirbelprothesen ist an sich bekannt. So sind in der US-PS 4 599 086, in der DE-OS 23 65 873 und in der EP 179 695 Anschlußstücke bei Wirbelprothesen mit fester Länge beschrieben, während gemäß der DE-OS 37 29 600 Anschlußstücke durch winkelförmige Stützkörper vorgesehen sind, die ihrerseits durch einen mittigen längenverstellbaren Abstandhalter verbunden sind. Die in der DE-OS 23 65 873 beschriebenen Anschlußstücke sind entlang eines Großteils des Umfangs der Stützplatte angeordnet, wodurch es infolge von mehreren in den Wirbelkörper eindringenden Knochenschrauben zu Spannungen, Ausbrüchen und Absplitterungen im Knochen kommen kann. Auch muß eine große Wundöffnung geschaffen werden, um die Anschlußstücke rund um den Wirbelkörper zu verschrauben. In der DE-OS 37 29 600 ist andererseits nur ein Anschlußstück an den Wirbelkörper in Form des senkrechten Teils eines winkelförmigen Stützkörpers mit einer Durchbrechung für eine Knochenschraube beschrieben. Bei einer Ausführung dieser Art ist

eine zuverlässige Verbindung der Wirbelkörper im Hinblick auf Drehkräfte jedoch nicht gegeben, da die Stirnfläche des Wirbelkörpers mit dem waagrechten Teil des winkelförmigen Stützkörpers nicht auch direkt verbunden ist.

Günstig ist, wenn die Anschlußstücke gegenüber dem Abstandhalter nach außen versetzt und mit den Stützplatten über Verbindungsabschnitte verbunden sind. Dadurch ist eine sichere Aufnahme des angrenzenden Wirbelkörpers gegeben und der außermittige Abstandhalter rückt damit etwas unter die Stirnfläche des angrenzenden Rückenwirbels, was aus statischen Gründen wünschenswert ist. Nichtsdestoweniger verbleibt genügend Platz für ein etwaiges Implantat.

Nach einer anderen Ausführungsform der Erfindung sind die Anschlußstücke, die mindestens eine Durchbrechung für eine in den angrenzenden Wirbelkörper seitlich eindringende Knochenschraube aufweisen, auf der dem Abstandhalter gegenüberliegenden Seite der Stützplatten mit den Stützplatten verbunden. Der Aufnahmeraum für das Implantat ist dadurch auch bei eingesetzter Prothese für den Chirurgen von derselben Seite für etwaige Korrekturen zugänglich wie die Verschraubung mit den benachbarten Wirbelkörpern. Eine Längsverstellung muß dann allerdings mit dem Einsetzen vorgenommen und fixiert werden, oder der Zutritt zu dieser muß über eine Bohrung durch das Implantat erfolgen, will man die Wunde weiter klein halten.

In einer weiteren bevorzugten Ausführungsform ist vorgesehen, daß die Anschlußstücke je zwei außermittig angeordnete Durchbrechungen für zwei in den angrenzenden Wirbelkörper seitlich eindringende Knochenschrauben aufweisen. Bei dieser Ausführungsform können nötigenfalls dem Eindringen der Knochenschrauben in den Wirbelkörper hinderliche Dorne im Randbereich der Stützplatte weggelassen werden.

Vorzugsweise sind an den Stützplatten in den Aufnahmeraum gerichtete Dorne zur Verankerung des Implantats vorgesehen. Dadurch kann weitestgehend auf die Verwendung von Knochenzement (Palacos) zur Fixierung, zur Ummantelung und zum Ausfüllen von Zwischenräumen verzichtet werden. Beim Aushärten von Knochenzement treten bekanntlich Temperaturen bis zu 95°C auf, was zur Verbrennung der umliegenden Gewebestrukturen führt. Die erfindungsgemäß vorgesehenen Dornen sichern dagegen eine dauerhafte Fixierung des Implantats, insbesondere eines Knochenimplantats,

ohne Verwendung von Knochenzement.

Bei der obigen Ausführungsform ist es günstig, wenn die Dorne in Fortsetzung der zur Verankerung an den benachbarten stabilen Wirbelkörpern vorgesehenen Dorne angeordnet sein. Die Herstellung der Wirbelprothese wird dadurch erheblich vereinfacht, da die Dorne in Form von Doppelkegel in hiefür in den Stützplatten vorgesehene Bohrungen eingepreßt werden können.

Dabei ist es von Vorteil, wenn die Dorne radial außerhalb von Durchbrechungen der Stützplatten angeordnet sind. Die Dorne erstrecken sich vorzugsweise in einem Stück ober- und unterhalb der jeweiligen Stützplatte und sind symmetrisch, beispielsweise an den Eckpunkten eines gedachten Sechsecks, angeordnet. Die Durchbrechungen (die an sich aus der DE-OS 37 29 600 bekannt sind) liegen dann innerhalb der Seitenkanten des Sechsecks. Diese Durchbrechungen, etwa in Form von Bohrungen oder Schlitten, ermöglichen ein Zusammenwachsen der angrenzenden Wirbelkörper mit der Wirbelprothese und dem durch die Dorne fest verankerten Implantat, wogegen die in der DE-OS 37 29 600 beschriebenen Durchbrechungen nur ein Einwachsen der Knochensubstanz des Wirbelkörpers in die Prothese ermöglichen, da diese Prothese keine Möglichkeit zur Aufnahme eines Implantats, insbesondere eines Knochenimplantats, aufweist.

Vorzugsweise weisen die kegeligen Dorne eine Länge von 3 bis 50 mm auf. Da die Wirbelprothese bei Patienten aller Altersstufen und in allen Bereichen der Wirbelsäule verwendet werden kann, ist es vorteilhaft, die Größe der Wirbelprothese und damit auch der Dorne in, diesen unterschiedlichen Anwendungszwecken angepaßten, einigen verschiedenen Dimensionen vorzusehen. Bei Kleinkindern wird entsprechend der Größe der angrenzenden Wirbelkörper und des einzusetzenden Implantats demgemäß eine kleinere Abmessung der Wirbelprothese und der Dorne gewählt werden als bei Erwachsenen. Auch wird beispielsweise bei Ersatz eines Halswirbels eine andere Dimension der Wirbelprothese gewählt werden als bei Ersatz eines Lendenwirbels. Die Dorne sind zweckmäßigerweise mindestens so lang, daß sie die etwa 3 mm dicke, den Wirbelkörper stirnseitig abschließende harte Schicht durchdringen können. Die Länge der Dorne ist praktisch unbeschränkt, sie können den angrenzenden gesunden Wirbelkörper auch zur Gänze durchdringen und sogar bis in den nächsten Wirbelkörper dringen. Dies führt dann allerdings zu einer eingeschränkten Beweglichkeit der Wirbel-

säule. Die Länge der Dorne sollte daher, falls nicht aus irgendwelchen Gründen anders beabsichtigt, die Höhe des angrenzenden Wirbelkörpers nicht übersteigen.

Wenn die Stützplatten kreisförmig ausgebildet sind, wird deren Herstellung durch Drehen wesentlich vereinfacht. Eine sechseckige Form ist ebenfalls stabil und leicht herstellbar.

Nach einer günstigen Ausführungsform ist der außermittige Abstandhalter ratschenartig längenverstellbar. Meist ist vor der Operation nicht bekannt, welche genaue Länge der Wirbelprothese benötigt wird. Durch einen ratschenartigen Verstellmechanismus des Abstandhalters ist eine schnelle und genaue Anpassung der Wirbelprothese an den zu überbrückenden Abstand zwischen den beiden verbliebenen gesunden Wirbelkörpern gewährleistet. Der Ausdruck "ratschenartig" wie hier verwendet bedeutet, daß der Abstandhalter der Wirbelprothese in eine Richtung, vorzugsweise zusammenschiebend, verstellbar ist, während eine Bewegung in die Gegenrichtung durch Sperreinrichtungen blockiert ist, wodurch eine Nachjustierung der Länge im eingesetzten Zustand nach Aufhebung der Streckung der Wirbelsäule des Patienten im Sinne einer Verkürzung der Prothese mehr oder weniger automatisch erfolgen kann.

Der Vorgang bei der Operation mit Anpassung der Prothese läuft etwa wie folgt ab: Anhand von Daten aus vorhergehenden Untersuchungen, Röntgenbildern und Erfahrungswerten wählt der Chirurg die passende Dimension der Prothese aus. Die Wirbelsäule des Patienten wird gestreckt und der (die) zerstörte(n) Wirbelkörper(teile) wird (werden) entfernt. Die Länge und die Form des zwischen die Stützplatten der Prothese einzusetzenden Implantats wird bestimmt und das vorgesehene bzw. entnommene Implantat wird auf die benötigte Dimension gebracht. Das Implantat wird außerhalb des Körpers des Patienten in den Aufnahmeraum der weit geöffneten Prothese eingesetzt und die Prothese wird manuell zusammengeschoben, wobei die an der Innenseite der Stützplatten angeordneten Dornen bereits in das Implantat eindringen und dieses fixieren. Darauf wird die Prothese zwischen den verbliebenen angrenzenden gesunden Wirbelkörpern eingesetzt und die Streckung der Wirbelsäule des Patienten aufgehoben. Da es dabei zu einem erheblichen Druck auf die Wirbelkörper kommt, dringen die Dorne an der Innenseite der Stützplatten weiter in das Implantat ein und der Abstandhalter schiebt sich weiter zusammen bzw. bei einer

Ratsche rastet er "Zahn für Zahn" zusammen. Gleichzeitig dringen die an der Außenseite der Stützplatten vorgesehenen Dorne in die Stirnflächen der angrenzenden Wirbelkörper ein. Wenn die Stützplatten an den Stirnflächen der angrenzenden Wirbelkörper und des Implantats anliegen, werden gegebenenfalls Knochenschrauben zur zusätzlichen Sicherung durch die Durchbrechungen der Anschlußstücke geschraubt.

Gemäß einer bevorzugten Ausführungsform ist der außermittige Abstandhalter (ratschenartig ausgebildet oder nicht) durch zwei miteinander lösbar verbundene Schienen gebildet, die je mit einer Stützplatte fest verbunden sind. Dies erscheint als die einfachste und sicherste Konstruktion.

Dabei ist es weiters vorteilhaft, wenn zumindest eine der Schienen eine Führung für die Längsverschiebung der anderen Schiene aufweist. Ein Verkanten der beiden Schienen bei der Längsverschiebung wird dadurch verhindert.

Günstig ist es, wenn die Führung im den Stützplatten gegenüberliegenden Endbereich der Schienen vorgesehen ist. Diese Anordnung sichert auch bei maximaler Öffnung eine sichere Führung der beiden Schienen.

Weiters ist vorteilhaft, wenn die Führung durch einen die andere Schiene überspannenden Bügel gebildet ist. Dieser Bügel stellt selbst bei lockerer Verbindung der beiden Schienen eine Maßnahme zum praktisch unverlierbaren Festhalten der anderen Schiene dar.

Gemäß einer bevorzugten Ausführungsform ist die Führung dadurch gebildet, daß die eine Schiene mit den Längsrändern wenigstens auf einem Teil ihrer Länge flanschartig umgebogen oder abgewinkelt ist. Eine derartige Führung stellt sicher, daß die beiden Schienen bei lockerer Verbindung exakt in einer Linie geführt sind.

Auch ist es günstig, wenn die Schienen des Abstandhalters in einem Schnitt quer zur Längsachse der Wirbelprothese in Bezug auf diese Achse konvex gekrümmt sind. Durch eine derartige als besonders vorteilhaft angesehene Form ist eine höhere Festigkeit der Prothese in Längsrichtung gegeben.

Dabei ist es auch vorteilhaft, wenn auch die Anschlußstücke in einem Schnitt quer zur Längsachse der Wirbelprothese in Bezug auf diese Achse konvex gekrümmt sind. Dadurch wird auch eine bessere Anpassung der Anschlußstücke an die angrenzenden Wir-

belkörper gegeben. Wird diese Form noch mit kreisförmigen Stützplatten kombiniert, kann die gesamte Wirbelprothese einfach durch Drehen hergestellt werden.

Es ist weiters vorteilhaft, wenn die Schienen an den einander zugewandten Seiten mit ineinandergreifenden Zähnen versehen sind. Dadurch wird jeweils bei Einrasten eines Zahns auf einer Schiene in die entsprechende Vertiefung auf der anderen Schiene eine gewisse Fixierung des Abstandhalters gegeben.

Dabei ist günstig, wenn bei jeder Schiene die Flanken der Zähne auf der Seite, die der mit der Schiene fest verbundenen Stützplatte zugewandt ist, senkrecht sind und auf der Seite, die der anderen Stützplatte zugewandt ist, schräg abfallen. Derart ausgebildete Zähne auf den Schienen bewirken, daß der Abstandhalter zwar zusammenschiebbar ist, ein unbeabsichtigtes Ausziehen jedoch durch das Anliegen der senkrechten Flanken der Zähne aneinander verhindert wird.

Es ist auch von Vorteil, wenn jede Schiene des Abstandhalters nur in den an die beiden Längskanten anschließenden Randbereichen mit Zähnen versehen ist. Diese Ausführungsform ist dann besonders vorteilhaft, wenn die Schienen des Abstandhalters in einem Schnitt quer zu ihrer Längsachse bezüglich der Längsachse der Wirbelprothese konvex gekrümmt ausgebildet sind. Durch das Weglassen der Zähne im inneren Bereich der Schienen wird die Federwirkung beim Verbinden der Schienen verstärkt, da bei über die gesamte Schienenbreite verlaufenden Zähnen eine erhöhte Radialsteifigkeit der Schienen gegeben ist.

Weiters ist bevorzugt vorgesehen, daß die beiden Schienen mittels eines lösbaren Befestigungsmittels, z.B. eines Stiftes oder einer Schraube, miteinander verbunden sind. Bei lockerem Befestigungsmittel sind die beiden Schienen damit leicht verstellbar. Wenn die Prothese mit eingesetztem Implantat dann auf ihre endgültige Länge eingestellt ist, wird das Befestigungsmittel einfach festgezogen oder geschlossen und preßt dadurch die beiden Schienen des Abstandhalters fest gegeneinander. Ein unerwünschtes Verstellen der Prothese in der Länge ist damit praktisch unmöglich.

Auch ist es vorzuziehen, wenn alle Teile des Befestigungsmittels unverlierbar festgehalten sind. Dies kann bei einer Schraube etwa dadurch erreicht werden, daß diese nach ihrem Einsetzen an ihrem vom Kopf abgewandten Ende nietenartig flachge-

drückt wird. Da diese Schraube relativ klein und beim Einsetzen der Prothese nur locker befestigt ist, besteht die Möglichkeit, daß sie und/oder eine eventuelle Gegenmutter im Körper des Patienten verloren geht. Dies wird dadurch verhindert. Bei Verwendung eines anderen Befestigungsmittels, beispielsweise eines Stiftes, kann dieser mit einer der Schienen fest verbunden sein, durchragt jedenfalls die andere Schiene und kann beispielsweise auf dem herausragendem Abschnitt ein Gewinde aufweisen, auf welches eine Mutter aufgeschraubt ist. Das Ende des Stiftes kann dann ebenfalls nietenartig flachgedrückt werden, um hier die Mutter unverlierbar zu halten.

Vorzugsweise werden die Schienen bei loser Schraube durch eine unter dem Schraubenkopf angeordnete Feder, z.B. eine Blattfeder, federnd aneinandergedrückt, die zugleich eine Sicherung für die Schraube bildet. So werden die Schienen des Abstandhalters bereits bei loser Schraube in gewissen Maß zusammengepreßt, wodurch eine exakte Längsanpassung der Prothese erleichtert und ein "Klappern" der Schienen verhindert wird. Gleichzeitig wird ein ungewolltes Lockern der Schraube durch die Wirkung der Feder verhindert. Die Feder kann dabei beispielsweise in Form einer Schraubenfeder oder einer gebogenen Blattfeder vorgesehen sein.

Auch ist es günstig, wenn in der näher zur Längsachse der Wirbelprothese gelegenen Schiene eine Gewindebohrung zur Aufnahme der Verbindungsschraube vorgesehen ist. Da die verwendete Verbindungsschraube auf Grund der Abmessungen der Prothese klein sein muß und sie erst dann festgezogen werden soll, wenn die Prothese mit eingesetztem Implantat an der zu prothesierenden Stelle der Wirbelsäule des Patienten auf ihre endgültige Länge gebracht wurde, ist eine Gewindebohrung vorteilhafter als eine Gegenmutter. Das Festziehen der Schraube gestaltet sich einfacher, da keine spezielle Maßnahme zum Festhalten der Mutter benötigt wird.

In der weiter von der Längsachse der Wirbelprothese weg gelegenen Schiene kann dann vorteilhafter Weise ein von der Verbindungsschraube durchsetzter Längsschlitz vorgesehen sein. Dieser Längsschlitz ermöglicht ein einfaches, rasches und praktisch stufenloses (soweit es durch die Zähne "stufenlos" sein kann) Verstellen des Abstandhalters. An sich ist es aber auch möglich, in einer oder beiden Schienen in Längsrichtung mehrere Bohrungen in Abständen nebeneinander vorzusehen. Die Längenanpassung erfolgt dann dadurch, daß eine Schraube in jeweils miteinander

fluchtende Bohrungen eingeschraubt wird. Diese Lösung ist jedoch bei der Herstellung der Prothese mit erheblichen Mehraufwand verbunden, da alle Bohrungen der innenliegenden Schiene mit Innengewinden versehen werden müssen und auch der Zahnabstand mit dem Abstand der Bohrungen koordiniert werden muß, um ein vollständiges Übereinanderliegen der beiden Bohrungen zu gewährleisten.

Es ist auch von Vorteil, wenn der Kopf der Verbindungsschraube versenkt vorgesehen ist. Dadurch kann eine glatte Außenseite des Abstandhalters erreicht werden, was im Hinblick auf eine mögliche Verletzung des umliegenden Gewebes günstig ist.

Nach einer weiteren Ausführungsform sind die Schienen des Abstandhalters federnd zusammengehalten. Sie können dadurch außerhalb des Körpers des Patienten in der Länge verstellt werden, ohne daß ein Verrutschen beim Einsetzen erfolgt. Nach Einsetzen der Prothese können die Schienen dann durch die Art der auf den Schienen vorgesehenen Zähne nur mehr zusammengleiten, bis das Implantat innen an den Stützplatten anliegt. Es ist zwar hier auch die zusätzliche Absicherung durch ein zusätzliches Befestigungsmittel, wie eine Schraube, möglich, aber bei entsprechender Ausgestaltung der Feder nicht unbedingt erforderlich.

Insbesondere können die Schienen durch eine oder mehrere sie außen umgreifende C-förmige Federklammer(n) zusammengehalten werden. Derartige Federklammern lassen sich leicht aufsetzen und wieder entfernen, wodurch ein einfaches Öffnen der Prothese, z.B. bei Einsetzen eines falsch dimensionierten Implantats ermöglicht wird.

Dabei sind bei Verwendung von zwei Federklammern diese vorzugsweise an den Längskanten der Schienen vorgesehen und greifen in jeweils an der bezüglich der Längsachse der Wirbelprothese äußeren Fläche der äußeren Schiene und der inneren Fläche der inneren Schiene vorgesehene Längsnuten ein, wodurch sie gegen Verrutschen und Lösen gesichert sind und überdies vorstehende Teile vermieden werden können.

Günstig ist, wenn zwischen den Schienen ein in eine an der Innenseite der äußeren Schiene vorgesehene Vertiefung versenkbares, in ausgefahrener Stellung quer zur Vertiefung einstellbares federbelastetes Distanzstück vorgesehen ist. Ein derartiges Distanzstück, das gegebenenfalls in eine zweite weniger hohe Vertiefung einrasten kann, ermöglicht in seiner ausgefahrenen Stellung ein Öffnen der Wirbelprothese, etwa bei einem ein-

gesetzten falsch dimensionierten Implantat, ohne die Federklammern zu entfernen. Das Distanzstück drückt dann die beiden Schienen und die darauf befindlichen Zähne gegen die Federwirkung der Klammern so weit auseinander, daß die Zähne nicht mehr ineinandergreifen.

Dabei kann das Distanzstück durch den Steg eines T-förmigen Einsatzes gebildet sein, dessen Schenkel durch eine in der äußeren Schiene vorgesehene Bohrung nach außen hindurchragt. Dadurch ist eine einfache Verstellmöglichkeit des Distanzstückes, sowohl bei eingesetzter Prothese als auch außerhalb des Körpers des Patienten, durch ein entsprechend ausgebildetes Werkzeug, beispielsweise durch einen passenden Schlüssel, gegeben.

Es ist auch von Vorteil, wenn senkrecht von den Stützplatten aufeinander zu gerichtete und vorzugsweise aneinander anschließende Wände zur mindestens teilweisen Begrenzung des zwischen den Stützplatten vorgesehenen Aufnahme-raumes vorgesehen sind, wobei eine Wand auch von einer Schiene gebildet sein kann. Speziell wenn kein genügend großes körpereigenes Knochenimplantat zur Verfügung steht ist der Chirurg oft dazu gezwungen, mehrere kleinere Knochenstücke zu verwenden und diese mit Knochenzement zu verbinden. Dabei ist es oft günstig, wenn der Aufnahme-raum mit Wänden vorgesehen ist, da dann diese Knochenstücke ohne vorheriger Formgebung nur in den Aufnahme-raum eingefüllt und mit Knochenzement miteinander verbunden werden müssen. Die Verbindung durch den Knochenzement kann dabei entweder bei auseinandergenommener Prothese oder bei bereits an die Länge der zu überbrückenden Lücke angepaßter Prothese durch hiezu vorgesehene Durchbrechungen erfolgen. Am einfachsten entsprechen diese Wände der Form der Stützplatten, sodaß etwa auch bei kreisrunden Stützplatten eine hohlzylinderförmige Wand zur Begrenzung des Aufnahme-raums vorgesehen sein kann.

Gemäß einer bevorzugten Ausführungsform der vorliegenden Erfindung bildet je eine Stützplatte mit der mit ihr fest verbundenen Schiene und dem Anschlußstück eine integrale Einheit. Die Anzahl der Teile der Wirbelprothese wird dadurch verringert. Damit ist ein einfaches und rasches Zusammensetzen der Prothese vor dem Gebrauch möglich.

In diesem Falle kann dann die Einheit aus einem Stück herausgearbeitet sein. Speziell die Herstellung einer Prothese mit runden Stützplatten und gekrümmten Schienen und Anschluß-

stücken kann dann durch Drehen aus einem Rohling erfolgen. Dadurch ist ein sicherer und fester Aufbau der Einheit gewährleistet, ohne nachträglichen Schweiß-, Niet- oder Schraubverbindung. Verbindungen dieser Art können im Körper des Patienten nicht durch Bildung eines Lokalelementes korrodieren und Schwachstellen bilden. Als Rohling kann ein passendes Stück, beispielsweise aus einem Sonderstahl, z.B. aus (A)FM138-Stahl (US-Norm), verwendet werden.

Eine weitere Aufgabe der vorliegenden Erfindung ist es, eine Vorrichtung zur Handhabung der oben beschriebenen Wirbelprothese zu schaffen. Hierzu wird eine Vorrichtung, umfassend zwei zueinander parallele Arme mit Einsätzen als Arbeitsteile, mindestens eine Führungseinrichtung und eine Verstelleinrichtung verwendet, wobei die Arme der Vorrichtung durch die Führungseinrichtung bei einem Verstellen in einer Ebene parallel zueinander geführt werden und die Verstelleinrichtung ein kontrolliertes Einstellen des Abstandes der beiden Arme zueinander ermöglicht. Mit einer derartigen Vorrichtung wird das Einsetzen, Spreizen und gegebenenfalls das Entfernen der erfindungsgemäßen, in der Regel relativ kleinen, Wirbelprothese wesentlich vereinfacht, wenn ein Einsatz zum Befestigen einer Wirbelprothese benutzt wird. Einsätze für andere Zwecke, etwa zum Vorstechen der Löcher für die Dorne, erleichtern weiters das Operieren.

Am einfachsten kann die Führungseinrichtung und die Verstelleinrichtung jeweils durch Stäbe und die Verstelleinrichtung dabei durch ein Gewinde an einem Stab gebildet werden. Das Gewinde ermöglicht dabei ein einfaches und stufenloses Verstellen des Abstands zwischen den Armen. Es ist auch möglich, die Verstellung durch zwei gegenläufige Gewinde auf einem Stab vorzunehmen, wobei die beiden gegenläufigen Gewindeabschnitte dieses Stabes dann in entsprechende Gewinde in den Armen eingreifen.

Zur stabilen Führung auch bei stärkerer Belastung ist es vorteilhaft, wenn die Führungseinrichtung durch zwei zueinander parallele Stäbe, zweckmäßigerweise zu beiden Seiten der Verstelleinrichtung, gebildet wird.

Gemäß einer weiteren bevorzugten Ausführungsform ist auch zusätzlich eine Meßeinrichtung zur Bestimmung des Abstandes der beiden Arme vorgesehen. Dies vereinfacht die Auswahl der Größe der Wirbelprothese und auch die Vorfertigung des Implantats, da

der Abstand zwischen den verbleibenden Wirbelkörpern durch den Chirurgen rasch und genau bestimmt werden kann.

Bei einer Wirbelprothese mit Anschlußstücken und Durchbrechungen in diesen Anschlußstücken kann die Wirbelprothese durch Schrauben mit den Einsätzen zu deren Halterung derart verbunden sein, daß die Schrauben durch Bohrungen in den Einsätzen ragen und in Gewinden ruhen, die hier in den Bohrungen der Anschlußstücke der Wirbelprothese vorgesehen sind. Die Verwendung von Schrauben zur Befestigung der Wirbelprothese an den Einsätzen ermöglicht eine sichere und auch leicht lösbare Verbindung.

In einer weiteren bevorzugten Ausführungsform der Vorrichtung ist die der Wirbelprothese zugewandte Seite der zu deren Halterung bestimmten Einsätze an die äußere Form der Anschlußstücke der Wirbelprothese angepaßt und vorzugsweise sind die Einsätze an den Armen unverdrehbar gehalten. Dadurch wird bei an diesen Einsätzen an den Armen der Vorrichtung befestigter Wirbelprothese eine genaue Führung der Teile der Wirbelprothese beim Spreizen der Vorrichtung ermöglicht und ein eventuelles Verkanten des Abstandshalters der Wirbelprothese vermieden.

Die Erfindung wird nachfolgend anhand von in den Zeichnungen dargestellten bevorzugten Ausführungsbeispielen noch weiter erläutert.

Es zeigen:

Fig. 1 eine axonometrische Ansicht einer Wirbelprothese in auseinandergezogener Darstellung;

Fig. 2 eine Unteransicht der bezüglich der Längsachse der Wirbelprothese äußeren, in Fig. 1 unteren Hälfte dieser Wirbelprothese von Fig. 1;

Fig. 3 eine Wirbelprothese gemäß einer Ausführungsform mit Federn in zusammengebautem Zustand in axonometrischer Ansicht;

Fig. 4 eine Draufsicht der in Fig. 3 oberen (inneren) Hälfte der Wirbelprothese von Fig. 3;

Fig. 5 eine Draufsicht einer unteren (äußeren) Wirbelprothesen-Hälfte in einer Ausführungsform nach der Fig. 3 und 4;

Fig. 6 einen Grund- und Aufriß eines Distanzstückes für die Wirbelprothese von Fig. 5;

Fig. 7 eine andere Wirbelprothese mit kreisförmiger Stützfläche in axonometrischer Ansicht;

Fig. 8 eine Teilansicht einer modifizierten unteren (äußeren) Hälfte einer Wirbelprothese gemäß einer weiteren Ausführungsform;

Fig. 9 eine axionometrische Ansicht einer modifizierten oberen (inneren) Wirbelprothesen-Hälfte;

Fig. 10 eine schematische Seitenansicht einer eingesetzten Wirbelprothese gemäß Fig. 1 mit eingesetztem Implantat;

Fig. 11 eine Wirbelprothese gemäß einer weiteren Ausführungsform mit einer kompletten Umwandlung des Aufnahme- raumes für das Implantat in zusammengebautem Zustand in axonometrischer Ansicht;

Fig. 12 eine Draufsicht der in Fig. 11 oberen Hälfte der Wirbelprothese;

Fig. 13 eine Draufsicht der in Fig. 11 unteren Hälfte der Wirbelprothese;

Fig. 14 eine Wirbelprothese gemäß noch einer weiteren Ausführungsform in zusammengebautem Zustand in axonometrischer Ansicht;

Fig. 15 eine axionometrische Ansicht einer weiteren modifizierten oberen (inneren) Wirbelprothesen-Hälfte;

Fig. 16 eine axionometrische Ansicht noch einer anderen modifizierten unteren (äußeren) Wirbelprothesen-Hälfte;

Fig. 17 einen Grundriß eines Details der Fig. 16;

Fig. 18 eine Seitenansicht einer Vorrichtung zur Handhabung der Wirbelprothese;

Fig. 19 eine Draufsicht auf die Vorrichtung von Fig. 18; und

Fig. 20 einen anderen Einsatz.

In Fig. 1 ist eine Wirbelprothese 1 veranschaulicht, die im wesentlichen aus zwei Teilen oder Hälften besteht, die je eine integrale Einheit 2, 3 bilden. Jede dieser Einheiten 2, 3 besteht im wesentlichen aus einer z.B. sechseckigen Stützplatte 4 (auch beliebige andere Formen sind möglich), die über einen Verbindungsabschnitt 5 mit einem dazu vorzugsweise rechtwinkelig angeordnetem Anschlußstück 6 verbunden ist. Auf der anderen Seite des Verbindungsabschnittes 5 erstreckt sich vorzugsweise senkrecht weg von diesem eine Schiene 7 bzw. 8, wobei die beiden Schienen 7, 8 miteinander einen längenverstellbaren Abstandhalter 9 bilden, wie weiter unten noch näher erläutert wird. Zwischen

den Stützplatten 4 ist ein Aufnahmeraum für das Implantat gebildet, der seitlich nur teilweise von den Schienen 7 und 8 begrenzt ist und für den die Stützplatten 4 die Deck- und Bodenflächen bilden. Die Länge dieses Aufnahmeraumes ist durch gegeneinander Verschieben der Schienen variierbar. Bei Befestigung der beiden Schienen 7 und 8 aneinander wird dessen Größe festgelegt und stabil gehalten.

Die Stützplatten 4 weisen, vom Rand bzw. von den Ecken etwas nach innen versetzt, sich in beide Richtungen erstreckende Dorne 10 zur Verankerung in angrenzende Wirbelkörper (nicht gezeigt) bzw. Dorne 11 zur Verankerung eines eingesetzten Implantats (ebenfalls nicht gezeigt) auf. Die Dorne 10 und 11 können selbstverständlich versetzt und an anderen Stellen vorgesehen werden, genauso wie sie auch andere Formen in Ansicht und Querschnitt haben können. Besonders bei künstlichen Implantaten sind die in den Aufnahmeraum ragenden Dorne 11 nicht unbedingt erforderlich, ja bei besonders harten Implantaten auch gar nicht zweckmäßig.

Weiters sind in den Stützplatten 4 Durchbrechungen 12 vorgesehen, um ein Zusammenwachsen des zwischen den Stützplatten 4 befindlichen Implantats mit den angrenzenden Wirbelkörpern zu ermöglichen. Nachdem ein Durchwachsen erwünscht ist, sind solche Durchbrechungen vorteilhaft. Die Anzahl und Ausbildung dieser Durchbrechungen können beliebig variieren, jedoch ist es zur Erzielung einer Umwachsung zwecks festerer Verankerung der Prothese zweckmäßig, wenigstens zwei Durchbrechungen vorzusehen.

In den Anschlußstücken 6 sind Bohrungen 13 vorgesehen, durch die (nicht dargestellte) Knochenschrauben von der Seite her in die angrenzenden Wirbelkörper eingeschraubt werden können. Diese Bohrungen können auch mit Gewinden versehen sein. Derartige Anschlußstücke müssen überhaupt nicht vorgesehen werden, weil auch schon mit den Dornen 10 alleine eine stabile Verbindung herstellbar ist. Sie tragen aber zu einer weiteren Stabilisierung bei.

Die beiden Schienen 7, 8 des längenverstellbaren Abstandhalters 9 sind auf den einander zugewandten Seiten mit Zähnen 14 versehen, deren Flanken jeweils auf der Seite, die der mit der Schiene 7 bzw. 8 verbundenen Stützplatte 4 zugewandt ist, senkrecht sind und auf der anderen Seite schräg abfallen. In der bezüglich der - durch die Mitten der Stützplatten 4 definierten -

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Längsachse der Wirbelprothese 1 äußeren Schiene 8 ist ein Längsschlitz 15 und in der inneren Schiene 7 ist eine Gewindebohrung 16 vorgesehen. Der Längsschlitz 15 ist so dimensioniert, daß der Schaft einer Verbindungsschraube 17 darin in Längsrichtung verschiebbar ist. Beim Zusammenbau der Wirbelprothese 1 wird diese durch den Längsschlitz 15 hindurchgeschobene Verbindungsschraube 17 gegen die Federwirkung einer zwischen der Schiene 8 und dem Kopf der Schraube 17 angeordneten Blattfeder 18, die abgerundete Kanten aufweist, in die in der Schiene 7 vorgesehenen Gewindebohrung 16 eingeschraubt. Das aus der Gewindebohrung 16 herausragende Ende kann dann nietenartig flachgedrückt werden und so unverlierbar in den Schienen festgehalten sein. Es wäre zwar auch möglich innen glatte Schienen 7 und 8 zu verwenden, jedoch stellt dies eine erheblich höhere Anforderung an die Befestigungsmittel. Auch beliebig anders geformte ineinandergreifende Vorsprünge und Vertiefungen könnten an den einander zugeordneten Flächen der Schienen 7 und 8 vorgesehen sein, jedoch stellen Zahnreihen ein Optimum dar.

Wie aus Fig. 2 ersichtlich ist, weist die Schiene 8 der äußeren integralen Einheit 3 im Randbereich des Längsschlitzes 15 einen Absatz oder eine Schulter 19 auf, auf dem bzw. der die Blattfeder 18 und die Unterseite des Kopfes der Verbindungsschraube 17 aufliegen, wodurch der Kopf gegenüber der Unter- oder Außenseite der Schiene 8 versenkt angeordnet ist.

Die in Fig. 3 gezeigte Wirbelprothese 1 besteht im wesentlichen aus den gleichen Teilen wie die in Fig. 1 gezeigte Wirbelprothese. Unterschiedlich ist hier die lösbare Verbindung der beiden mit Zähnen 14 versehenen Schienen 7, 8 der beiden Hälften 2, 3 der Wirbelprothese 1. Auf der Oberseite der oberen Schiene 7 und der Unterseite der unteren Schiene 8 sind benachbart den Längsrändern Längsnuten 20 vorgesehen, in die zwei C-förmige Federklammern 21 eingreifen, um in diesen gelagert zu werden und so die Schienen 7, 8 zusammenzudrücken. Bei der Wirbelprothese 1 nach Fig. 3 muß somit nach dem Einsetzen des Implantats (nicht gezeigt) kein Zusammenschließen der Schienen 7, 8 durch eine Verbindungsschraube 17 vorgenommen werden.

Fig. 4 zeigt die obere integrale Einheit 2 der Wirbelprothese 1 gemäß Fig. 3, deren Anschlußstück 6 im Bereich der Knochenschrauben-Bohrung 13 eine Einsenkung 22 (strichliert gezeigt) für die versenkte Anbringung der durch die Bohrung 13 dringende

Knochenschraube (nicht gezeigt) aufweist. Eine gleichartige Ausbildung weist auch die Bohrung der Einheit 3 auf.

Die in Fig. 5 gezeigte untere integrale Einheit 3 besitzt zusätzlich an der mit den Zähnen 14 versehenen Oberseite der unteren (äußeren) Schiene 8 zwei zueinander senkrecht liegende, einander schneidende rechteckige Vertiefungen 23, 23' und eine im Schnittpunkt beider Vertiefungen vorgesehene Bohrung 24. Die beiden Vertiefungen 23, 23' sind dabei unterschiedlich tief. Im vorliegenden Fall ist beispielsweise die parallel zur Längsachse der Einheit liegende Vertiefung 23' so tief, daß sie den (strichliert eingezeichneten) Steg 25 eines in Ansicht T-förmigen Distanzstückes 26 (siehe Fig. 6) zur Gänze aufnehmen kann, sodaß bei zusammengebauter Prothese die Zähne 14 der beiden eng aneinander anliegenden Schienen 7, 8 ineinandergreifen können, wogegen die Vertiefung 23 wesentlich seichter ist. Wenn der Steg 25 des Distanzstückes 26 (Fig. 6) von außen gegen die Wirkung der Federklammern 21 nach innen, in Richtung auf die andere Schiene 7, gedrückt und um 90° gedreht wird, sodaß der Steg 25 in der seichteren Vertiefung 23 zu liegen kommt, liegen die Zähne 14 der anderen Schiene 7 am Steg 25 auf und können nicht mehr in die Zähne 14 der Schiene 8 eingreifen. Dadurch ist ein Öffnen der Wirbelprothese 1 ohne Entfernung der C-förmigen Federklammern 21 möglich und die beiden Schienen 7, 8 können übereinander geschoben werden.

Fig. 6 zeigt im einzelnen in Auf- und Grundriß das in Fig. 5 verwendete Distanzstück 26 mit dem Steg 25 und einem Schenkel 27 mit einer sechseckigen Ausnehmung 28 in seiner Stirnfläche. Der Schenkel 27 ragt dann bei zusammengebauter Prothese durch die Bohrung 24 und kann mit einem geeigneten Schlüssel von außen leicht gedreht werden.

In Fig. 7 ist eine weitere Ausführungsform gezeigt, bei der die Stützplatten 4 der beiden Einheiten 2, 3 der Wirbelprothese 1 kreisrund ausgebildet sind. Diese Ausbildung erleichtert das Herausarbeiten der Einheiten 2, 3 aus einem Stück, beispielsweise durch Drehen. Im übrigen entspricht die Wirbelprothese 1 von Fig. 7 jener gemäß Fig. 1.

Fig. 8 zeigt in Teilansicht eine Modifikation der Schienen 7 bzw. 8 (hier: der Schiene 8) der Wirbelprothese 1, wobei die Zähne 14 nur in den beiden Längs-Randbereichen 29, 30 der Schienen vorgesehen sind. Weiters sind die Schienen in einem

Schnitt quer zu der Längsachse der Wirbelprothese konvex gekrümmt. Zur leichteren Herstellung mittels Drehen liegt der Krümmungsmittelpunkt der Schiene im Mittelpunkt der Stützplatten.

In Fig. 9 ist eine weitere Abwandlung der integralen Einheit 2 der Wirbelprothese 1 gezeigt, wobei im einzelnen die obere oder innere Schiene 7 auf mehreren Abschnitten ihrer Länge in Richtung zur Schiene 8 der integralen Einheit 3 (nicht gezeigt) umgebogene oder abgewinkelte Teile 31 aufweist, die eine Führung für die andere, untere Schiene 8 bilden.

Fig. 10 zeigt in schematischer Seitenansicht eine Wirbelprothese 1, hier jene gemäß Fig. 1, im eingesetzten Zustand, wobei die bügelartige Konfiguration der Wirbelprothese 1 ersichtlich ist. Weiters sind auch ein zwischen den Stützplatten 4 befindliches Implantat 32 sowie zwei durch die Bohrungen 13 in den Anschlußstücken 6 seitlich in die angrenzenden, gesunden Wirbelkörper (z.B. 34) eingeschraubte Knochenschrauben 33 ersichtlich. Ebenso sind strichliert die in die Wirbelkörper 34 bzw. in das Implantat 32 eindringenden Dorne 10 und 11 dargestellt.

Die in Fig. 11 gezeigte Wirbelprothese 1 besteht im wesentlichen aus den gleichen Teilen wie die in Fig. 1 gezeigte Wirbelprothese 1. Unterschiedlich sind hier die von den Stützplatten 4 aufeinander zu gerichteten und aneinander anschließenden Wände 4' und 4", die zwei ineinanderschließbare Schachteln bilden, welche den Aufnahmeraum für das Implantat umschließen.

Fig. 12 und Fig. 13 zeigen die beiden Hälften 2 und 3 der Wirbelprothese 1 von Fig. 12 mit den Wänden 4' und 4" in Ansicht.

Die in Fig. 14 gezeigte Wirbelprothese 1 besteht ebenfalls im wesentlichen aus den gleichen Teilen wie die in Fig. 1 gezeigte Wirbelprothese 1, jedoch sind hier die Anschlußstücke 6 auf der dem Abstandhalter 9 gegenüber liegenden Seite der Stützplatten 4 angeordnet. Weiters sind die Stützplatten 4 rund und die Schienen 7, 8 des Abstandhalters 9 und die Anschlußstücke 6 sind in einem Schnitt quer zu ihrer Längsachse bezüglich der Längsachse der Wirbelprothese konvex gekrümmt ausgebildet und zwar mit einem Krümmungsradius, dessen Mittelpunkt mit den Mittelpunkten der Stützplatten 4 zusammenfällt. Diese Schienen bilden gleichzeitig Teilwände des Aufnahmeraumes. Bei dieser Ausführungsform ist in der äußeren Schiene (hier 7) nur eine Bohrung für einen Schraubenschaft als Befestigungsmittel dargestellt. Hier wird der bewegliche und zum Lockern der Längsverbinding der

beiden Schienen 7 und 8 vorgesehene Teil der Befestigungsmittel, etwa der Schraubenkopf oder eine Mutter an der unteren (nicht sichtbaren) Seite der Schiene 8 vorzugsweise versenkt liegen. Will man jedoch bei eingesetztem Implantat dann eine Fixierung oder Lockerung erreichen, muß das Implantat durchbohrt werden, um ein Werkzeug, wie einen Schlüssel, hindurchführen zu können.

In Fig. 15 ist noch eine Abwandlung der integralen Einheit 2 der Wirbelprothese 1 gezeigt, wobei hier beispielsweise die obere oder innere Schiene 7 im der Stützplatte 4 gegenüberliegenden Endbereich auf beiden Längsseiten je einen seitlichen Vorsprung 31a aufweist, die nach unten in Richtung zur Schiene 8 der integralen Einheit 3 (nicht gezeigt) ragen oder abgewinkelt sind. Die Vorsprünge 31a bilden dabei hier eine seitliche Führung für die andere, untere Schiene 8. Gleichzeitig kann natürlich auch die nicht gezeigte Schiene 8 ebensolche Vorsprünge 31a aufweisen. Auch können die Vorsprünge 31a an ihren Enden hakenartige Fortsätze zum Hintergreifen der Schiene 8 besitzen.

Fig. 16 zeigt eine weitere Ausführungsform der integralen Einheit 3 der Wirbelprothese 1, wobei hier die Führung für die andere Schiene 7 durch einen im Endbereich der äußeren Schiene 8 angeordneten Bügel 31b gebildet wird, der die andere Schiene 7 im zusammengebauten Zustand mit Spiel (um ein Übereinander"ratschen" der Zähne der Schienen 7, 8 bei der Längsverstellung zu ermöglichen) umgreift. Der Bügel 31b hat außer der Führungsfunktion auch den Zweck, die beiden integralen Einheiten 3, aus denen die Wirbelprothese besteht, im noch nicht fixierten Zustand besser zusammenzuhalten.

Die Einheit 3 weist hier überdies ein modifiziertes Anschlußstück 6 mit zwei seitlichen Durchbrechungen 13 zur Aufnahme von zwei Knochenschrauben (nicht gezeigt) in zwei seitlich vorragenden Zungen auf. Die für das Eindringen dieser Knochenschrauben hinderlichen nach außen ragenden Dorne 10 sind hier weggelassen (vgl. auch Fig. 17).

In Fig. 18 wird eine Vorrichtung 35 gezeigt, die während der Operation in Verbindung mit der Wirbelprothese 1 (nicht gezeigt) zum Einsatz kommt. Die Vorrichtung 35 besteht aus zwei in einer Ebene liegenden zueinander parallelen Armen 36 und 37, die miteinander durch zwei parallele Führungsstäbe 40 und einen vorzugsweise in der gleichen Ebene liegenden Verstellstab 41 verbunden sind. Die Endbereiche der Arme 36 und 37 weisen jeweils

Gewindebohrungen 46 zur Befestigung von auswechselbare Einsätzen 38, 39 mittels Schrauben 47 auf. Diese beiden Einsätze besitzen ihrerseits jeweils sowohl eine Bohrung 48 zur versenkten Aufnahme der Schraube 47, als auch eine Bohrung 43 zur Aufnahme von Schrauben 42 zur Befestigung der Wirbelprothese 1 (hier nicht gezeigt) über deren Anschlußstücke 6. Die Führungsstäbe 40 sind in Bohrungen im Arm 36 eingepreßt und in Bohrungen 49 im Arm 37 verschiebbar. Weiters weisen die Führungsstäbe 40 an ihren Enden Anschläge 50 auf. Der Verstellstab 41 weist eine aufgepreßte Rändelscheibe 52, eine Schulter 51 und einen Gewindeabschnitt 44 auf, welcher Gewindeabschnitt in eine Gewindebohrung 53 im Arm 37 eingreift. Der Abschnitt zwischen der Schulter 51 und der Rändelscheibe 52 ist dabei in einer Bohrung 54 im Arm 36 frei drehbar. Bei Drehung der Rändelschraube 52 werden dann je nach Drehrichtung die beiden Arme 36 und 37 zueinander parallel auseinander- oder zusammengeschoben, wodurch in weiterer Folge bei aufgeschraubter Wirbelprothese der Abstandhalter 9 der (nicht gezeigten) Wirbelprothese 1 geöffnet oder geschlossen wird. Weiters ist auf einem der Führungsstäbe 40 eine Skalierung 45 zum Ablesen des Abstandes der beiden Arme 36 und 37 voneinander bzw. der benötigten Größe der Wirbelprothese oder des Implantats angebracht.

Für die Ausbildung der Führung sind eine Vielzahl von Varianten verfügbar. Die einfachste ist nur ein drehbarer Stab, der gleichzeitig das Gewinde für die Verstelleinrichtung trägt. Wenn die Bauhöhe groß genug ist, wird auch ein Herausragen der Führungsstäbe nicht erforderlich. Auch müssen keine Stäbe verwendet werden - so ist etwa auch eine geschlitzte Platte, in deren Schlitz der Gewindestab drehbar angeordnet ist, eine mögliche Alternative. Auch die Verstelleinrichtung kann anders ausgebildet sein.

In Fig. 19 ist ersichtlich, daß die der Wirbelprothese 1 zugewandte Seite der Einsätze 38 und 39 an die runde Form der Anschlußstücke 6 aus Fig. 14 angepaßt ist. Eine andere Form der Anpassung wäre etwa durch eine entsprechende Ausnehmung in der Einsatzvorderfläche erzielbar. Weiters ist im Endbereich des Arms 36 eine Nut 55 zur Aufnahme eines Vorsprungs 56 am Einsatz 38 ersichtlich, was als ein Beispiel für eine zusätzliche Fixierung gegen Verdrehung gegenüber dem Arm (hier 36) von vielen Möglichkeiten anzusehen ist.

Fig. 20 zeigt einen anderen Einsatz, der analog zu einer Stützplatte 4 mit Außendornen ausgebildet ist. Er dient zum Einstecken der Löcher in die angrenzenden Wirbelkörper zur Vorbereitung des Einsatzes der Wirbelprothese.

Diese Einsätze können auf beliebige Weise an den Armen der Vorrichtung befestigt sein, etwa auch durch Schwalbenschwanznut und -feder. Verzichtet man auf die anderen Anwendungen und will man nur die Wirbelprothese halten, so können die in Fig. 18 und 19 gezeigten Einsätze auch einstückig mit den Armen verbunden sein. Eine Variation dieser Einsätze ist aber vorteilhaft, schon wegen der Möglichkeit der Benutzung eines Einsatzes nach Fig. 20. Weitere praktische Einsätze können benutzt werden, z.B. Meßeinsätze in Verbindung mit einer Skala zwischen ihnen und dergleichen.

Die Vorrichtung wird bei der Operation nun wie folgt verwendet:

Der durch die Wirbelprothese zu überbrückende Abstand wird durch Einsetzen der Vorrichtung 35 in die Wirbelsäule, Spreizen der Vorrichtung 35 mittels Drehen der Rändelschraube 52 bis die Außenseiten der Einsätze 38 bzw. 39 an den Stirnflächen benachbarter Wirbelkörper anliegen und Ablesen des Abstandes A auf der Skalierung 45 festgestellt. Sodann wird die Vorrichtung 35 wieder aus der Wirbelsäule entfernt und eine geeignete Wirbelprothese 1 wird anhand des nun bekannten Abstandes A ausgewählt. Es können nun mit Einsätzen gemäß Fig. 20 die Löcher für die Außendorne in den angrenzenden Wirbelkörperflächen vorgestochen werden. Die Wirbelprothese 1 wird nun in teilweise zusammengesobenem Zustand mittels der in die (hier als Gewindebohrungen ausgeführten) Durchbrechungen 13 der Anschlußstücke 6 eingreifenden Schrauben 42 mit der Vorrichtung 35 verbunden, mittels der Vorrichtung 35 in die Wirbelsäule eingebracht und dort bis auf die richtige Länge gespreizt. Noch vorteilhafter ist es, die Wirbelprothese gleich in der gemessenen Länge an die Einsätze zu ihrer Halterung zu befestigen. Die Prothese kann somit unter geringem Kraftaufwand sofort sicher in der Wirbelsäule verankert werden. Nach Entfernen der Vorrichtung 35 aus der Operationswunde können sodann Knochenschrauben durch die Durchbrechungen 13 der Anschlußstücke 6 geschraubt werden und die entgültige Fixierung der Länge vorgenommen werden.

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Die am meisten bevorzugte Ausführungsform der Wirbelprothese 1 ist jene nach Fig. 7, bei welcher jedoch an Stelle der dort angeführten flachen Schienen 7 und 8 die konvex gekrümmten Schienen nach Fig. 8 benutzt werden. Dabei liegt der Krümmungsmittelpunkt dieser Schienen im Mittelpunkt der jeweiligen Stützplatte 4. Die beiden Teile 2 und 3 der Wirbelprothese 1 sind aus einem Stück gedreht und die ebenfalls gedrehten Doppeldorne 10, 11 sind nachträglich eingesetzt.

P A T E N T A N S P R Ü C H E :

1. Wirbelprothese zum Einsetzen anstelle eines oder mehrerer zerstörter Wirbelkörper, mit zwei Stützplatten (4) zur Anlage an den Stirnflächen benachbarter stabiler Wirbelkörper, wobei die Stützplatten Verankerungsmittel (10) zur Verankerung in diesen Wirbelkörpern aufweisen und durch mindestens einen in der Länge verstellbaren Abstandhalter (9) verbunden sind, dadurch gekennzeichnet, daß der Abstandhalter (9) außermittig bezüglich der durch die Mittelpunkte der Stützplatten (4) definierten Längsachse der Wirbelprothese (1) angeordnet ist, wobei zwischen den Stützplatten (4) ein freier Aufnahmeraum zur Aufnahme eines Implantats (32) aus natürlichem und/oder künstlichem Material belassen ist.
2. Wirbelprothese nach Anspruch 1, dadurch gekennzeichnet, daß die Verankerungsmittel (10) Dorne sind.
3. Wirbelprothese nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Stützplatte (4) mindestens eine Durchbrechung (12) aufweist.
4. Wirbelprothese nach Anspruch 3, dadurch gekennzeichnet, daß die Durchbrechung (12) kreisrund ausgebildet ist.
5. Wirbelprothese nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß in ungefährrer Fortsetzung des außermittigen Abstandhalters (9) Anschlußstücke (6), die mindestens eine Durchbrechung (13) für eine in den angrenzenden Wirbelkörper seitlich eindringende Knochenschraube (33) aufweisen, mit den Stützplatten (4) verbunden sind.
6. Wirbelprothese nach Anspruch 5, dadurch gekennzeichnet, daß die Anschlußstücke (6) gegenüber dem Abstandhalter (9) nach außen versetzt und mit den Stützplatten (4) über Verbindungsabschnitte (5) verbunden sind.
7. Wirbelprothese nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß Anschlußstücke (6), die mindestens eine Durchbrechung (13) für eine in den angrenzenden Wirbelkörper seitlich eindringende Knochenschraube (33) aufweisen, auf der dem Abstandhalter (9) gegenüberliegenden Seite der Stützplatten (4) mit den Stützplatten (4) verbunden sind.
8. Wirbelprothese nach einem der Ansprüche 5 bis 7, dadurch gekennzeichnet, daß die Anschlußstücke (6) je zwei außermittig

angeordnete Durchbrechungen (13) für zwei in den angrenzenden Wirbelkörper seitlich eindringende Knochenschrauben (33) aufweisen.

9. Wirbelprothese nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß an den Stützplatten (4) in den Aufnahme- raum gerichtete Dorne (11) zur Verankerung des Implantats (32) vorgesehen sind.

10. Wirbelprothese nach Anspruch 9, dadurch gekennzeichnet, daß die Dorne (11) in Fortsetzung von zur Verankerung an den benachbarten stabilen Wirbelkörpern vorgesehenen Dornen (10) angeordnet sind.

11. Wirbelprothese nach Anspruch 9 oder 10, dadurch gekennzeichnet, daß die Dorne (10, 11) radial außerhalb von Durchbrechungen (12) der Stützplatten (4) angeordnet sind.

12. Wirbelprothese nach einem der Ansprüche 9 bis 11, dadurch gekennzeichnet, daß die Dorne (10, 11) eine Länge von 3 bis 50 mm aufweisen.

13. Wirbelprothese nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, daß die Stützplatten (4) kreisförmig oder sechseckig ausgebildet sind.

14. Wirbelprothese nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, daß der außermittige Abstandhalter (9) ratschenartig längenverstellbar ist.

15. Wirbelprothese nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, daß der außermittige Abstandhalter (9) durch zwei miteinander lösbar verbundene Schienen (7, 8) gebildet ist, die je mit einer Stützplatte (4) fest verbunden sind.

16. Wirbelprothese nach Anspruch 15, dadurch gekennzeichnet, daß zumindest eine der Schienen (7 bzw. 8) eine Führung (31, 31a, 31b) für die Längsverschiebung der anderen Schiene (8 bzw. 7) aufweist.

17. Wirbelprothese nach Anspruch 16, dadurch gekennzeichnet, daß die Führung (31a, 31b) in den Stützplatten (4) gegenüberliegenden Endbereich der Schienen (7 bzw. 8) vorgesehen ist.

18. Wirbelprothese nach Anspruch 16 oder 17, dadurch gekennzeichnet, daß die Führung (31a) durch einen die andere Schiene (8 bzw. 7) überspannenden Bügel (31b) gebildet ist.

19. Wirbelprothese nach Anspruch 16 oder 17, dadurch gekennzeichnet, daß die Führung (31) dadurch gebildet ist, daß die eine Schiene (7 bzw. 8) mit den Längsrändern wenigstens auf einem Teil

ihrer Länge flanschartig umgebogen oder abgewinkelt ist.

20. Wirbelprothese nach einem der Ansprüche 15 bis 19, dadurch gekennzeichnet, daß die Schienen (7, 8) des Abstandhalters (9) in einem Schnitt quer zur Längsachse der Wirbelprothese (1) in Bezug auf diese Achse konvex gekrümmt sind.

21. Wirbelprothese nach Anspruch 20, dadurch gekennzeichnet, daß auch die Anschlußstücke (6) in einem Schnitt quer zur Längsachse der Wirbelprothese (1) in Bezug auf diese Achse konvex gekrümmt sind.

22. Wirbelprothese nach einem der Ansprüche 15 bis 21, dadurch gekennzeichnet, daß die Schienen (7, 8) an den einander zugewandten Seiten mit ineinandergreifenden Zähnen (14) versehen sind.

23. Wirbelprothese nach Anspruch 22, dadurch gekennzeichnet, daß bei jeder Schiene (7, 8) die Flanken der Zähne (14) auf der Seite, die der mit der Schiene fest verbundenen Stützplatte (4) zugewandt ist, senkrecht sind und auf der Seite, die der anderen Stützplatte (4) zugewandt ist, schräg abfallen.

24. Wirbelprothese nach Anspruch 22 oder 23, dadurch gekennzeichnet, daß jede Schiene (7, 8) des Abstandhalters (9) nur in den an die beiden Längskanten anschließenden Randbereichen (29, 30) mit Zähnen (14) versehen ist.

25. Wirbelprothese nach einem der Ansprüche 15 bis 24, dadurch gekennzeichnet, daß die beiden Schienen (7, 8) mittels eines lösbaren Befestigungsmittels, z.B. eines Stiftes oder einer Schraube (17), miteinander verbunden sind.

26. Wirbelprothese nach Anspruch 25, dadurch gekennzeichnet, daß alle Teile des Befestigungsmittels unverlierbar festgehalten sind.

27. Wirbelprothese nach Anspruch 25 oder 26, dadurch gekennzeichnet, daß die Schienen (7, 8) bei loser Schraube (17) durch eine unter dem Schraubenkopf angeordnete Feder, z.B. einer Blattfeder (18), federnd aneinandergedrückt werden, die zugleich eine Sicherung für die Schraube (17) bildet.

28. Wirbelprothese nach einem der Ansprüche 25 bis 27, dadurch gekennzeichnet, daß in der näher zur Längsachse der Wirbelprothese (1) gelegenen Schiene (7) eine Gewindebohrung (16) zur Aufnahme der Verbindungsschraube (17) vorgesehen ist.

29. Wirbelprothese nach einem der Ansprüche 25 bis 28, dadurch gekennzeichnet, daß in der weiter von der Längsachse der

Wirbelprothese (1) weg gelegenen Schiene (8) ein von der Verbindungsschraube (17) durchsetzter Längsschlitz (15) vorgesehen ist.

30. Wirbelprothese nach einem der Ansprüche 15 bis 29, dadurch gekennzeichnet, daß der Kopf der Verbindungsschraube (17) versenkt vorgesehen ist.

31. Wirbelprothese nach einem der Ansprüche 15 bis 24, dadurch gekennzeichnet, daß die Schienen (7, 8) des Abstandhalters (9) federnd zusammengehalten sind.

32. Wirbelprothese nach Anspruch 31, dadurch gekennzeichnet, daß die Schienen (7, 8) durch eine oder mehrere sie außen umgreifende C-förmige Federklammern (21) zusammengehalten sind.

33. Wirbelprothese nach Anspruch 32, dadurch gekennzeichnet, daß zwei Federklammern (21) an den Längskanten der Schienen vorgesehen sind, die in jeweils an der bezüglich der Längsachse der Wirbelprothese (1) äußeren Fläche der äußeren Schiene (8) und der inneren Fläche der inneren Schiene (7) vorgesehene Längsnuten (20) eingreifen.

34. Wirbelprothese nach einem der Ansprüche 31 bis 33, dadurch gekennzeichnet, daß zwischen den Schienen (7, 8) ein in eine an der Innenseite der äußeren Schiene vorgesehene Vertiefung (23') versenkbares, in ausgefahrener Stellung quer zur Vertiefung (23') einstellbares federbelastetes Distanzstück (26) vorgesehen ist.

35. Wirbelprothese nach Anspruch 34, dadurch gekennzeichnet, daß das Distanzstück (26) durch den Steg (25) eines T-förmigen Einsatzes gebildet ist, dessen Schenkel (27) durch eine in der äußeren Schiene vorgesehenen Bohrung (24) nach außen hindurchragt.

36. Wirbelprothese nach einem der Ansprüche 1 bis 35, dadurch gekennzeichnet, daß senkrecht von den Stützplatten (4) aufeinander zu gerichtete und vorzugsweise aneinander anschließende Wände (4', 4'') zur mindestens teilweisen Begrenzung des zwischen den Stützplatten (4) vorgesehenen Aufnahmeraumes vorgesehen sind, wobei eine Wand auch von einer Schiene (7, 8) gebildet sein kann.

37. Wirbelprothese nach einem der Ansprüche 15 bis 36, dadurch gekennzeichnet, daß je eine Stützplatte (4) mit der mit ihr fest verbundenen Schiene (7 bzw. 8) und dem Anschlußstück (6) eine integrale Einheit (2 bzw. 3) bildet.

38. Wirbelprothese nach Anspruch 37, dadurch gekennzeichnet, daß die Einheit (2 bzw. 3) aus einem Stück herausgearbeitet ist.

39. Vorrichtung zur Handhabung der Wirbelprothese nach einem der Ansprüche 1 bis 38, umfassend zwei zueinander parallele Arme (36, 37) mit Einsätzen (38, 39) als Arbeitsteile, mindestens eine Führungseinrichtung (40) und eine Verstelleinrichtung (41), wobei die Arme (36, 37) der Vorrichtung durch die Führungseinrichtung (40) bei einem Verstellen in einer Ebene parallel zueinander geführt werden und die Verstelleinrichtung (41) ein kontrolliertes Einstellen des Abstandes der beiden Arme (36, 37) zueinander ermöglicht.

40. Vorrichtung nach Anspruch 39, dadurch gekennzeichnet, daß die Führungseinrichtung (40) und die Verstelleinrichtung (41) jeweils durch Stäbe und die Verstelleinrichtung (41) dabei durch ein Gewinde (44, 44') an einem Stab gebildet wird.

41. Vorrichtung nach Anspruch 40, dadurch gekennzeichnet, daß die Führungseinrichtung (40) durch zwei zueinander parallele Stäbe zweckmäßigerweise zu beiden Seiten der Verstelleinrichtung (41) gebildet wird.

42. Vorrichtung nach einem der Ansprüche 39 bis 41, dadurch gekennzeichnet, daß zusätzlich eine Meßeinrichtung (45) zur Bestimmung des Abstandes der beiden Arme (36, 37) vorgesehen ist.

43. Vorrichtung nach einem der Ansprüche 39 bis 43 zur Handhabung der Wirbelprothese nach einem der Ansprüche 5 bis 38, dadurch gekennzeichnet, daß bei Einsätzen (38, 39) zur Befestigung der Wirbelprothese (1) diese durch Schrauben (42) mit den Einsätzen (38, 39) verbunden ist, wobei die Schrauben (42) durch Bohrungen (43) in den Einsätzen (38, 39) ragen und in Gewinden ruhen, die in jeweils einer der Durchbrechung (13) der Anschlußstücke (6) der Wirbelprothese (1) vorgesehen sind.

44. Vorrichtung nach einem der Ansprüche 39 bis 43 für Wirbelprothesen nach einem der Ansprüche 5 bis 38, dadurch gekennzeichnet, daß bei Einsätzen (38, 39) zur Befestigung der Wirbelprothese (1) die dieser zugewandte Seite der Einsätze (38, 39) an die äußere Form der Anschlußstücke (6) der Wirbelprothese (1) angepaßt und vorzugsweise die Einsätze (38, 39) an den Armen (36, 37) unverdrehbar gehalten sind.

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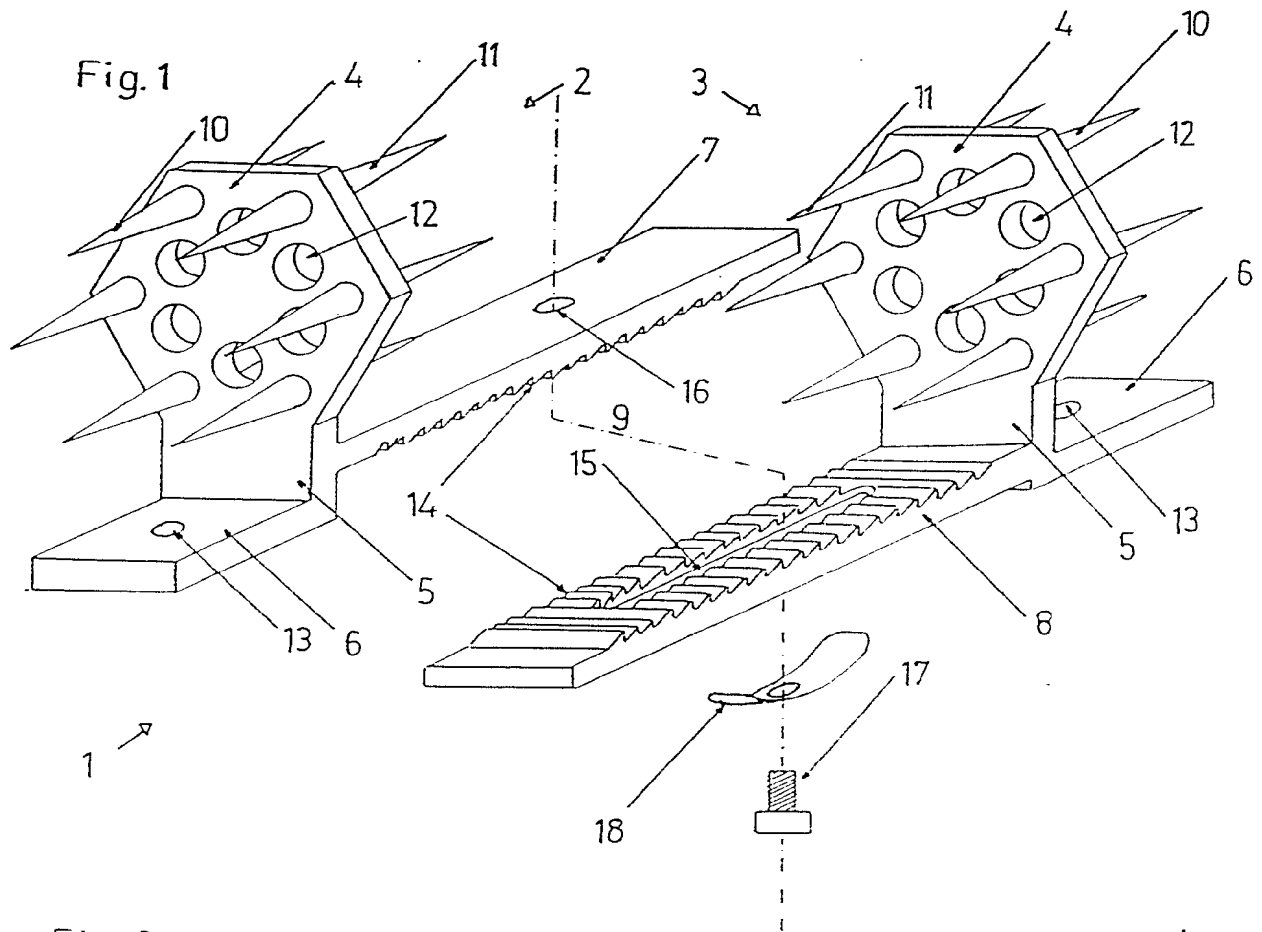
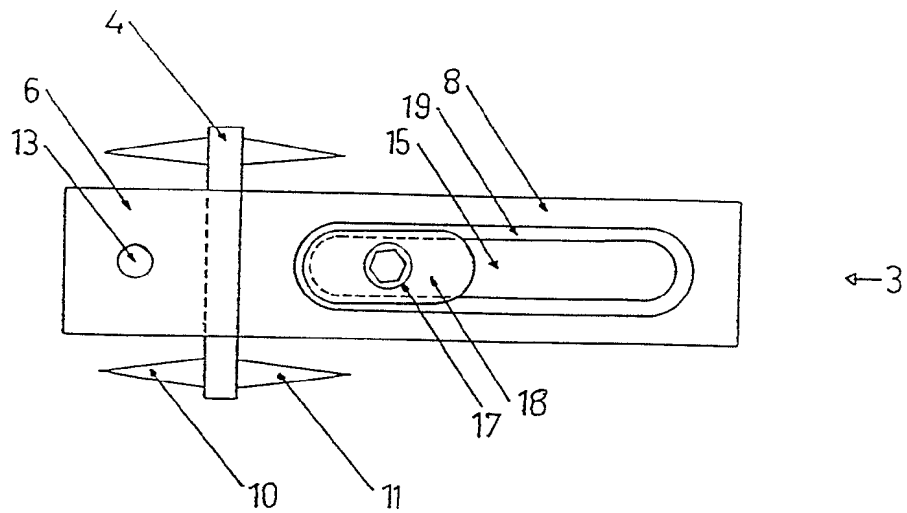
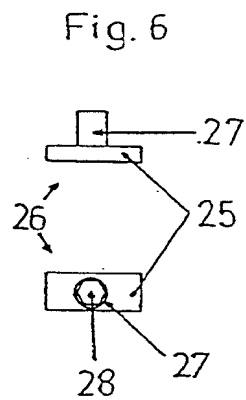
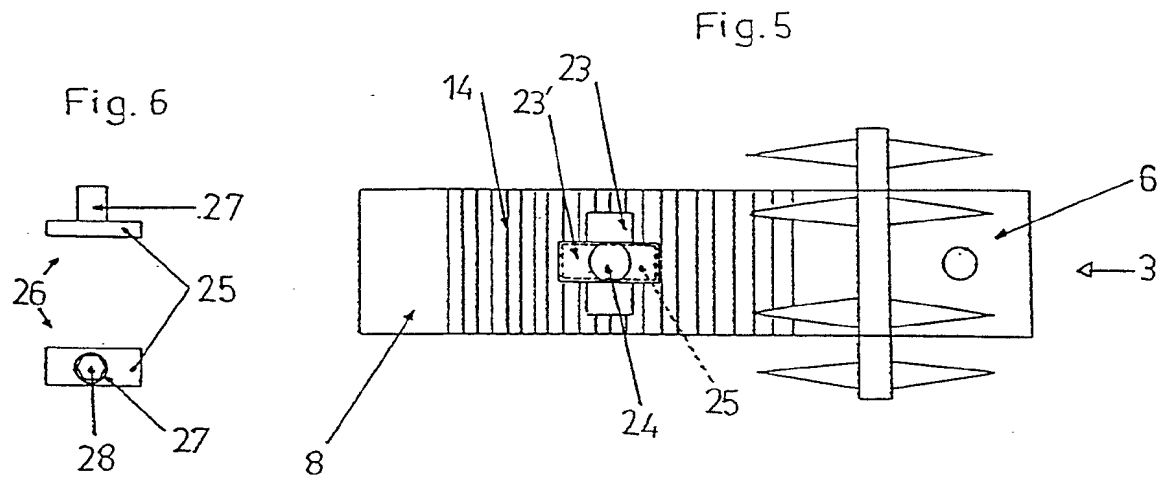
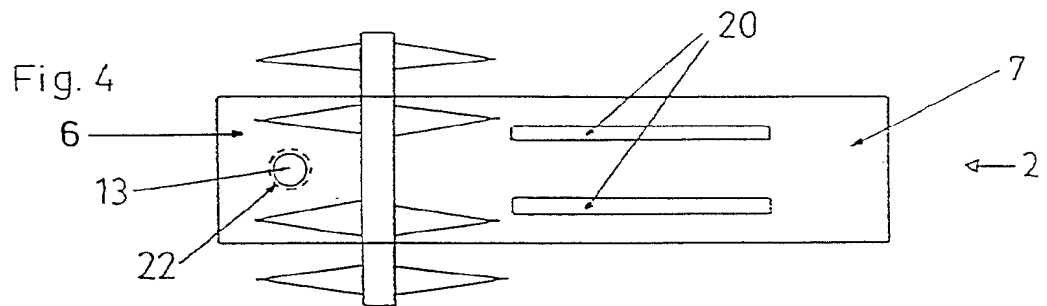
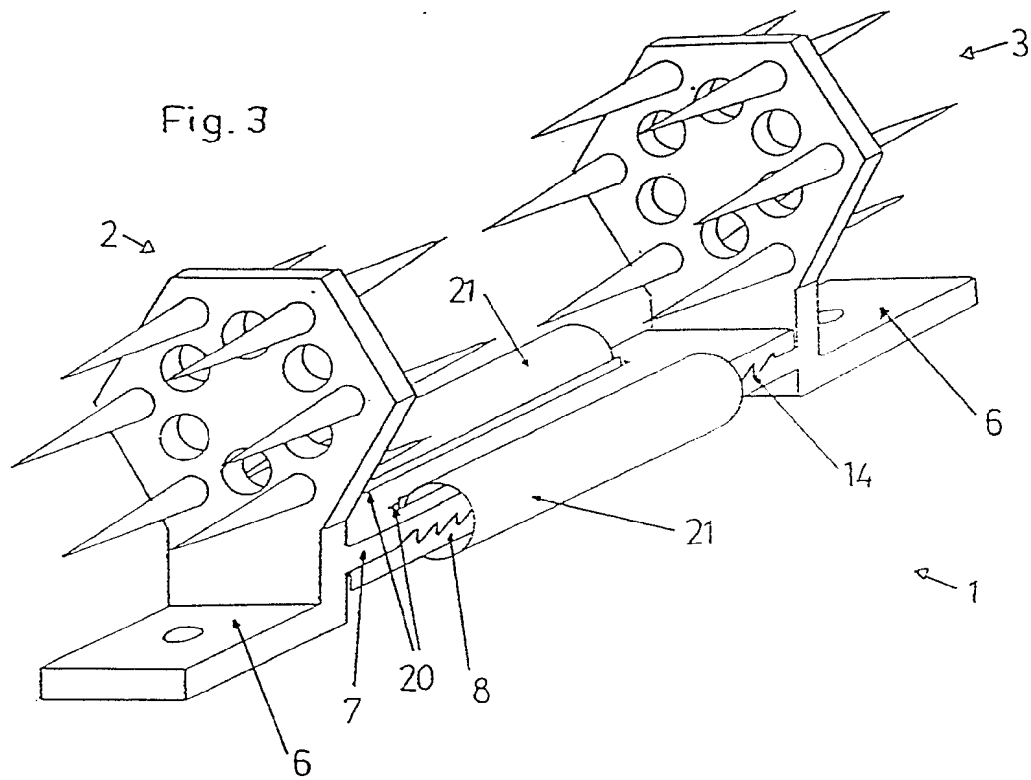


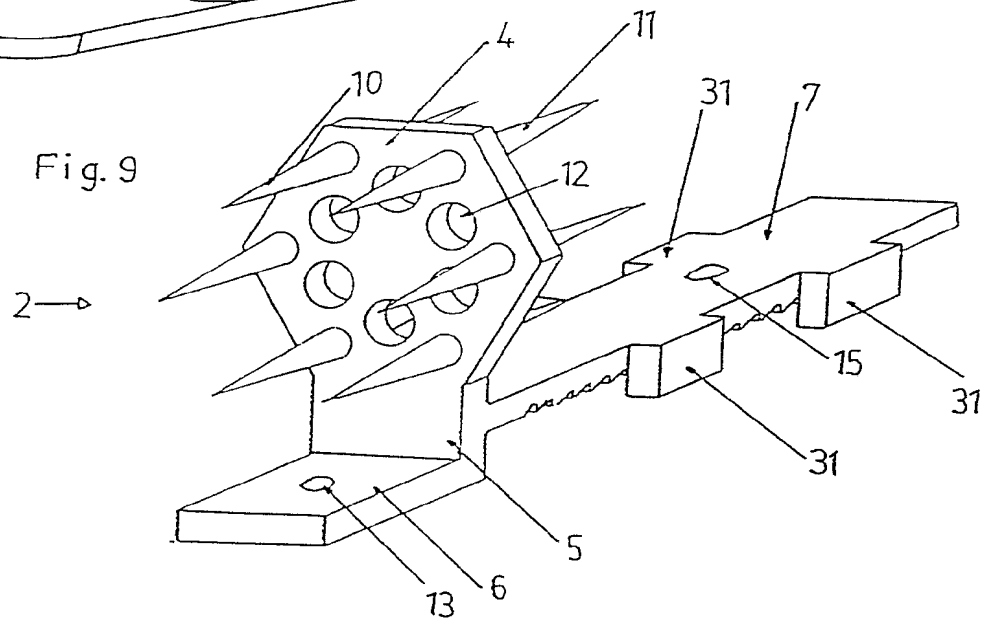
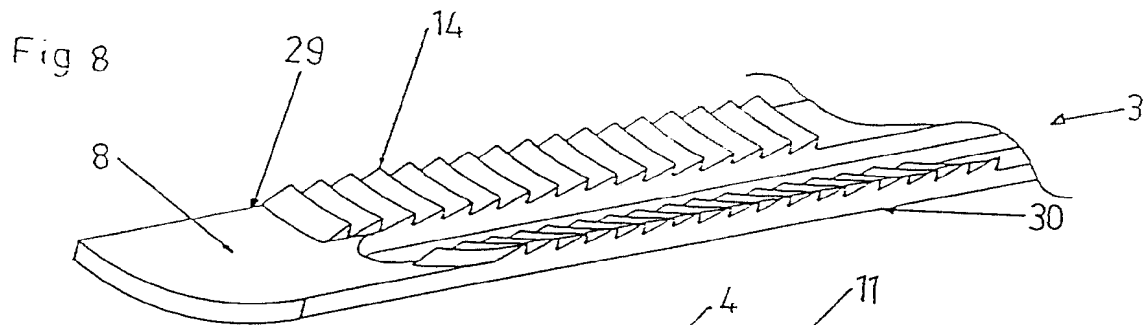
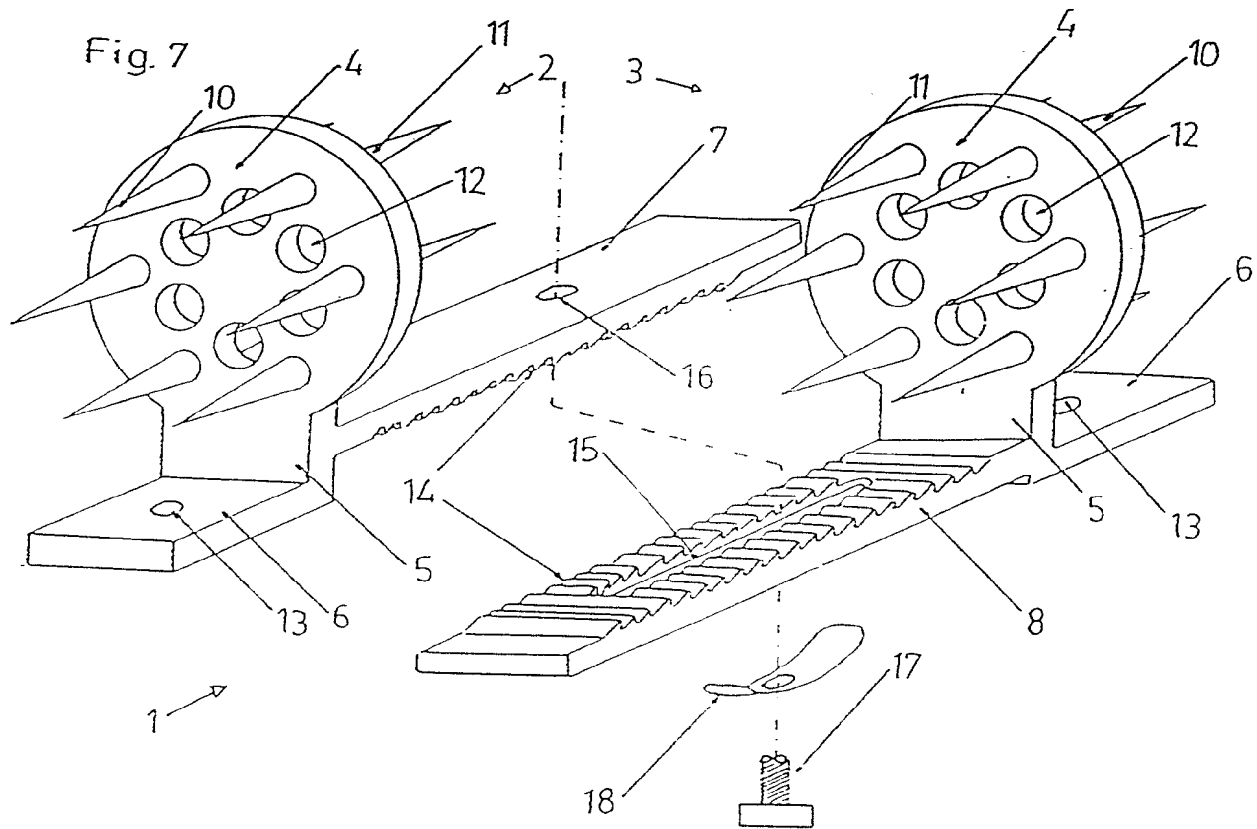
Fig 2



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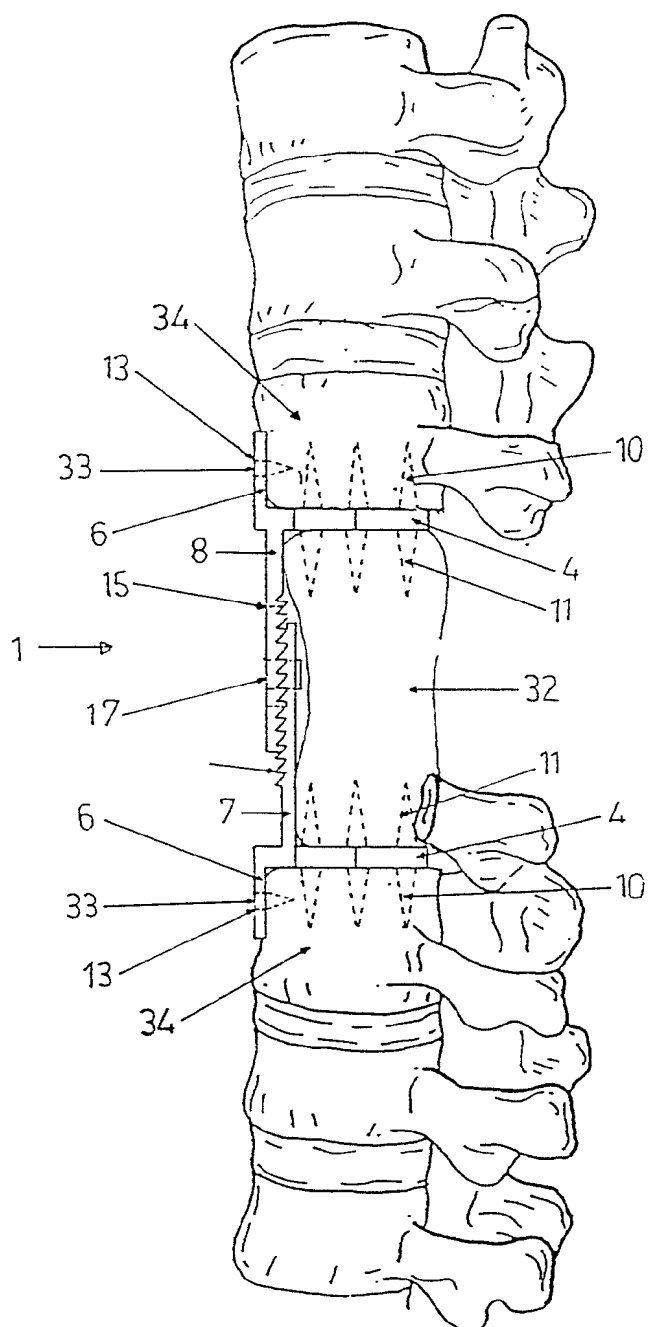


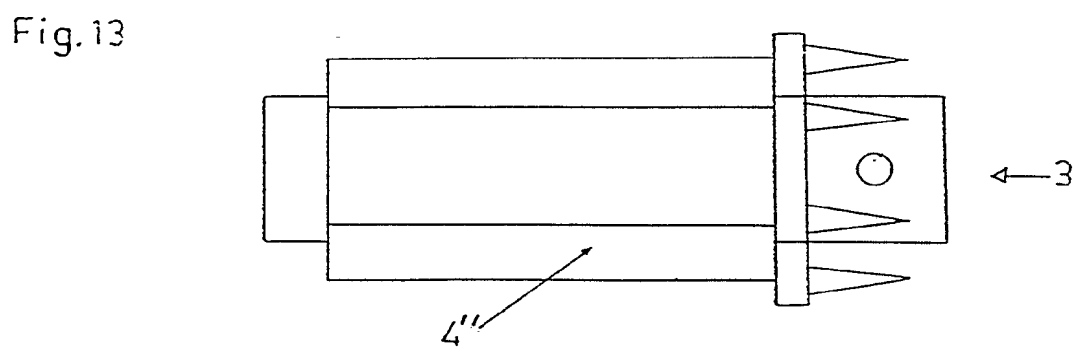
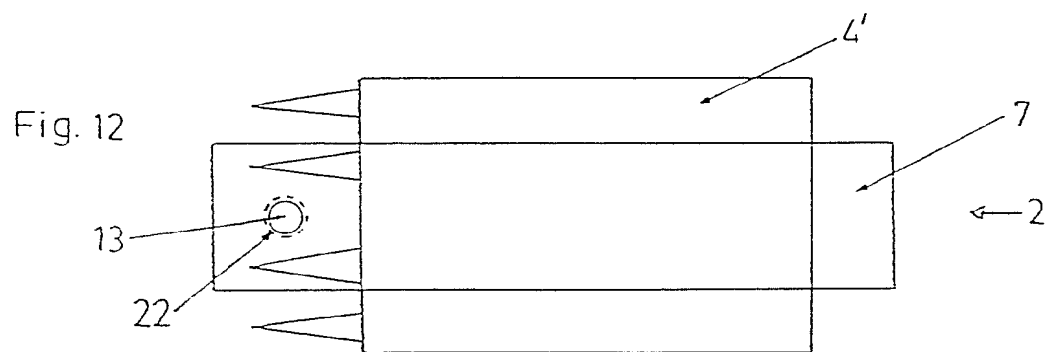
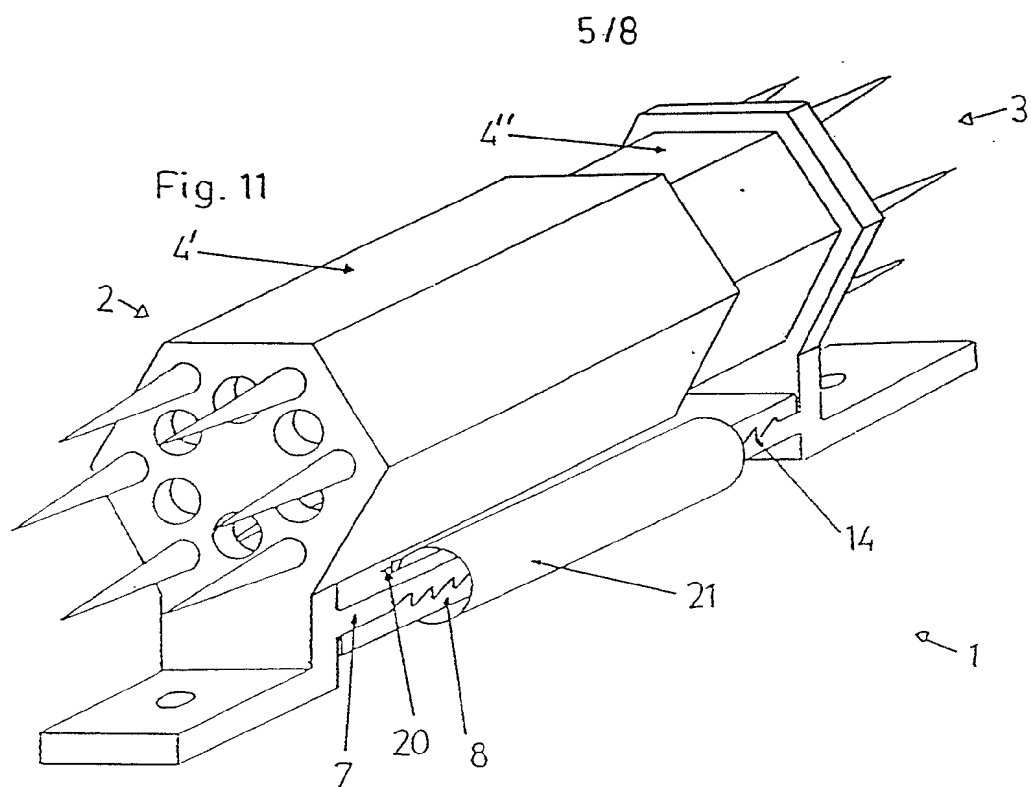
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4/8

Fig. 10





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Fig. 14

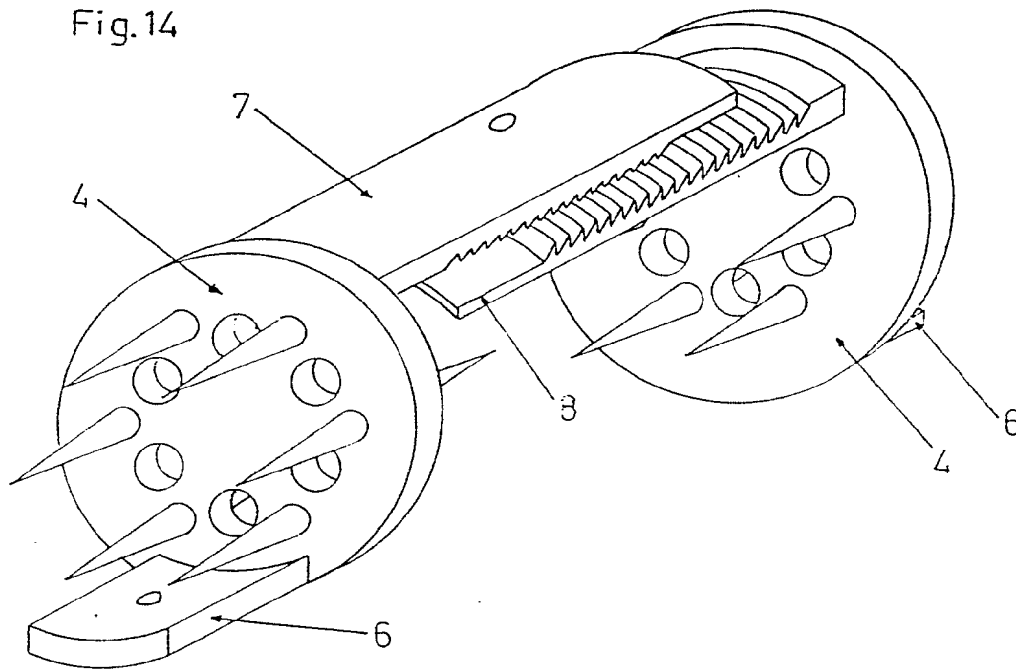
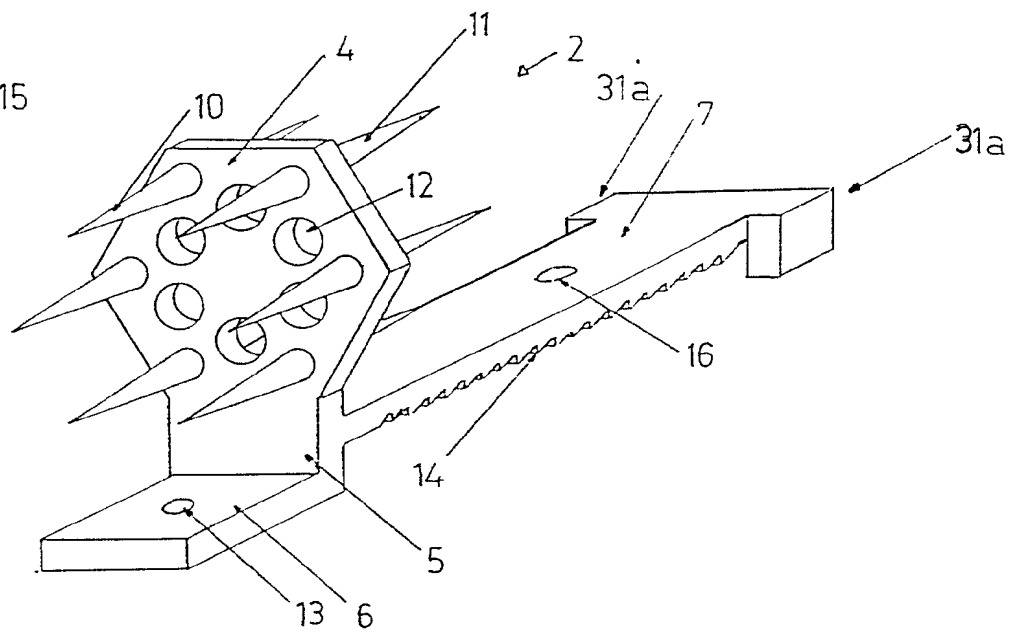
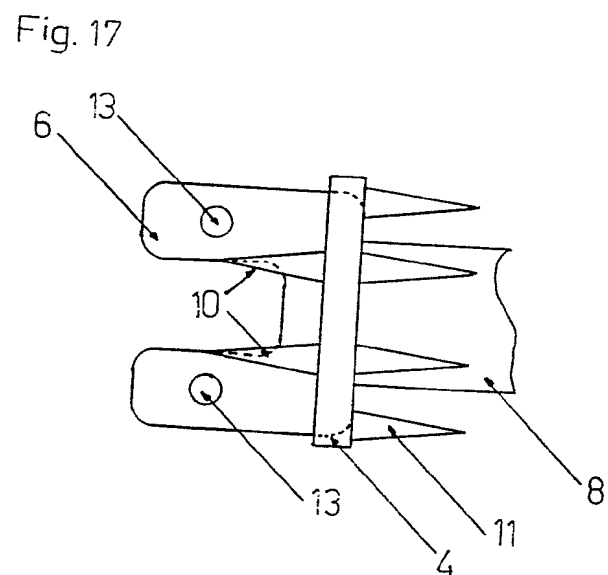
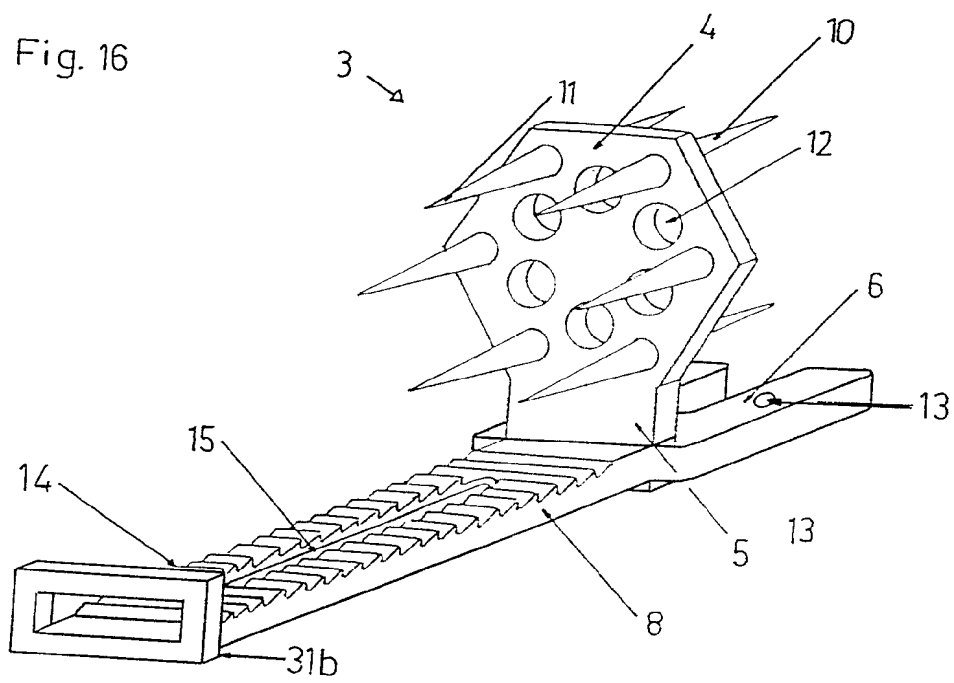


Fig. 15



7/8



8/8

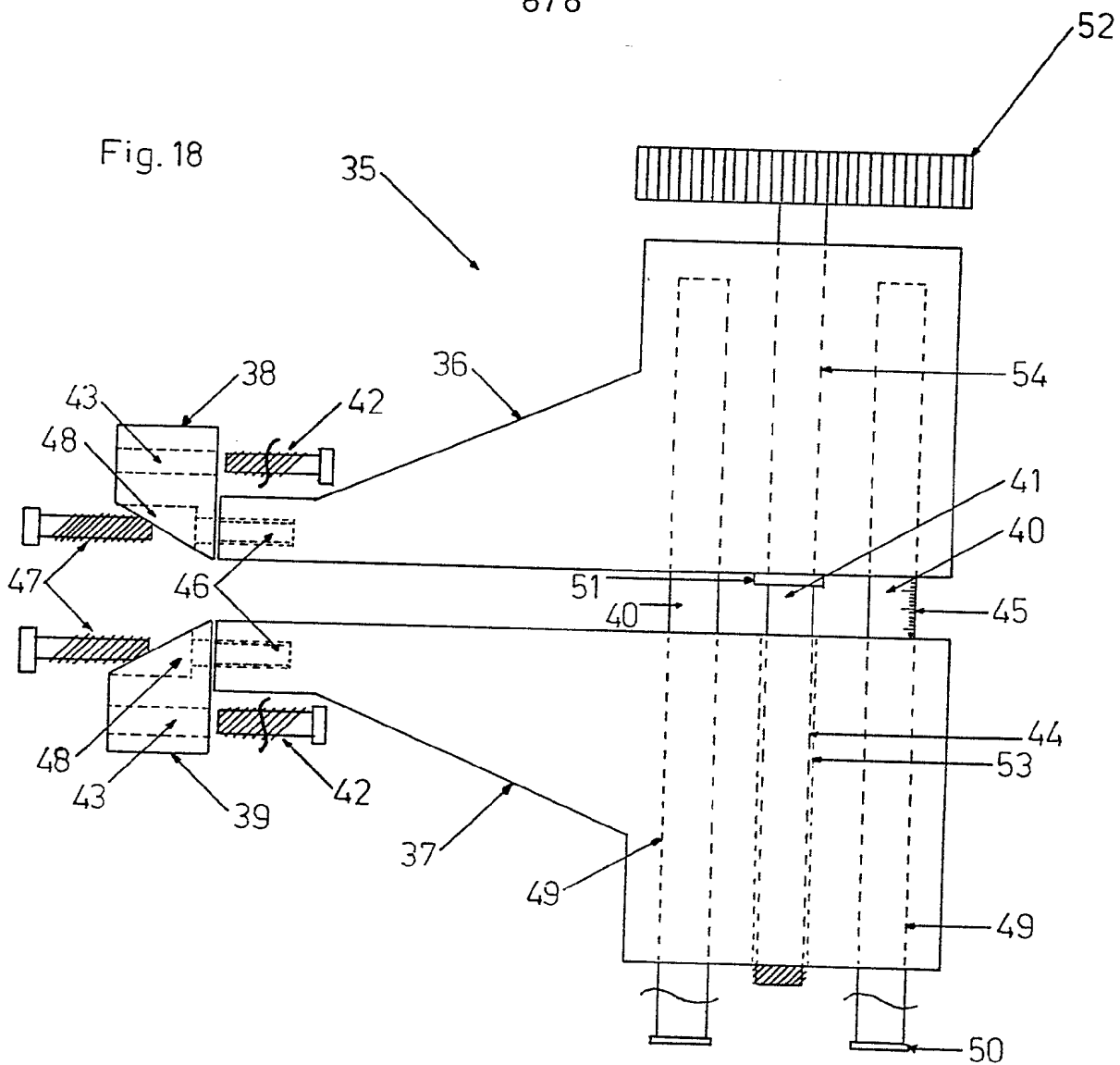


Fig. 19

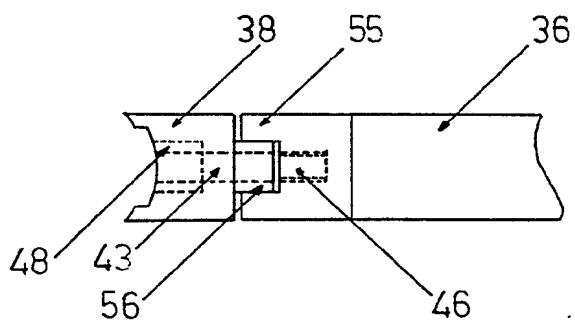
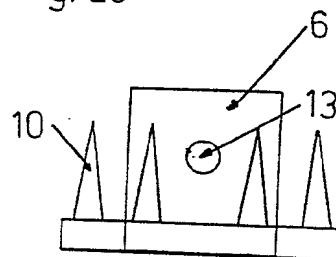


Fig. 20



INTERNATIONAL SEARCH REPORT

International Application No PCT/AT/ 91/00090

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. ⁵ A61F2/44 ; A61B17/60		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. ⁵	A61F ; A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	DE,A,3729600 (LUTZE, T) 16 March 1989 cited in the application see claims 1-5; figure 5 ---	1
A	US,A,4289123 (DUNN) 15 September 1981 see column 3, line 17 - line 44; claim 1; figure 1 ---	1
A	FR,A,2506605 (ULRICH) 03 December 1982 see page 9, line 9 - line 36; figures 3,4 ---	1
A	EP,A,0159007 (KLUGER) 23 October 1985 see abstract; claims 1,3,4; figures 1,2 -----	1,39
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 04 October 1991 (04.10.91)		Date of Mailing of this International Search Report 18 October 1991 (18.10.91)
International Searching Authority EUROPEAN PATENT OFFICE		Signature of Authorized Officer

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

AT 9100090
SA 49493

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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04/10/91

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A-3729600	16-03-89	None	
US-A-4289123	15-09-81	AU-A- 6883281	08-10-81
FR-A-2506605	03-12-82	DE-A- 3121271	23-12-82
		JP-A- 57203436	13-12-82
		US-A- 4445513	01-05-84
EP-A-0159007	23-10-85	DE-A- 3414374	24-10-85
		US-A- 4733657	29-03-88

I. KLASSIFIKATION DES ANMELDUNGSGEGENSTANDS (bei mehreren Klassifikationssymbolen sind alle anzugeben)⁶

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

Int.Kl. 5 A61F2/44 ; A61B17/60

II. RECHERCHIERTE SACHGEBIETERecherchierter Mindestprüfstoff ⁷

Klassifikationssystem

Klassifikationssymbole

Int.Kl. 5

A61F ; A61B

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Art. ⁹	Kennzeichnung der Veröffentlichung ¹¹ , soweit erforderlich unter Angabe der maßgeblichen Teile ¹²	Betr. Anspruch Nr. ¹³
A	DE,A,3 729 600 (LUTZE,T) 16. März 1989 in der Anmeldung erwähnt siehe Ansprüche 1-5; Abbildung 5 ---	1
A	US,A,4 289 123 (DUNN) 15. September 1981 siehe Spalte 3, Zeile 17 - Zeile 44; Anspruch 1; Abbildung 1 ---	1
A	FR,A,2 506 605 (ULRICH) 3. Dezember 1982 siehe Seite 9, Zeile 9 - Zeile 36; Abbildungen 3,4 ---	1
A	EP,A,0 159 007 (KLUGER) 23. Oktober 1985 siehe Zusammenfassung; Ansprüche 1,3,4; Abbildungen 1,2 ---	1,39

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Datum des Abschlusses der internationalen Recherche

04.OCTOBER 1991

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18. 10. 91

Internationale Recherchenbehörde

EUROPAISCHES PATENTAMT

Unterschrift des bevollmächtigten Bediensteten

GIMENEZ BURGOS R.

ANHANG ZUM INTERNATIONALEN RECHERCHENBERICHT ÜBER DIE INTERNATIONALE PATENTANMELDUNG NR.

AT 9100090
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In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patendokumente angegeben.
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Im Recherchenbericht angeführtes Patendokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
DE-A-3729600	16-03-89	Keine	
US-A-4289123	15-09-81	AU-A- 6883281	08-10-81
FR-A-2506605	03-12-82	DE-A- 3121271	23-12-82
		JP-A- 57203436	13-12-82
		US-A- 4445513	01-05-84
EP-A-0159007	23-10-85	DE-A- 3414374	24-10-85
		US-A- 4733657	29-03-88

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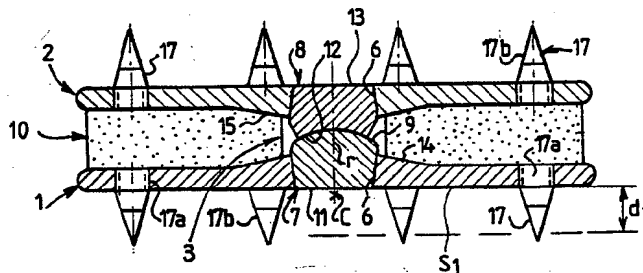
Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITE DE COOPERATION EN MATIERE DE BREVETS (PCT)

(51) Classification internationale des brevets ⁵ : A61F 2/44, A61L 27/00 A61F 2/30	A1	(11) Numéro de publication internationale: WO 94/04100 (43) Date de publication internationale: 3 mars 1994 (03.03.94)
(21) Numéro de la demande internationale: PCT/FR93/00825 (22) Date de dépôt international: 24 août 1993 (24.08.93) (30) Données relatives à la priorité: 9210232 24 août 1992 (24.08.92) FR (71) Déposant (pour tous les Etats désignés sauf US): SOCIÉTÉ DE FABRICATION DE MATÉRIEL ORTHOPÉDIQUE - SOFAMOR [FR/FR]; 5, rue Descamps, F-75016 Paris (FR). (72) Inventeur; et (75) Inventeur/Déposant (US seulement) : MAZDA, Keyvan [FR/FR]; 67, rue de Charenton, F-75012 Paris (FR). (74) Mandataire: MARTIN, Jean-Paul; Cabinet Lavoix, 2, place d'Estienne d'Orves, F-75441 Paris Cédex 09 (FR).		(81) Etats désignés: AU, BB, BG, BR, BY, CA, CZ, FI, HU, JP, KP, KR, KZ, LK, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, US, VN, brevet européen (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Publiée <i>Avec rapport de recherche internationale.</i>

(54) Title: INTERVERTEBRAL DISK PROSTHESIS**(54) Titre:** PROTHESE DISCALE INTERVERTEBRALE**(57) Abstract**

Prosthesis comprising two plates (1, 2) secured to the corresponding vertebrae (L4, L5), and a ball joint linking the plates to one another, its centre of rotation (C), in an anterior-posterior plane (OX, OY) being offset rearwards in the posterior part of the plates. The ball joint with reference to a transversal plane (OX, OZ) is located substantially in the middle of the plates, and with reference to a vertical plane (OY, OZ) is located under the plate (1) of the lower vertebra (L5). The prosthesis also includes an elastic intercalary cushioning ring (10) having an opening (10a) for the passage of the joint (3) and being lodged in the space delimited between the plates and around the joint. This positioning of the centre of curvature (C) prevents straining of the articular apophyses during movements of the vertebrae, while the elastic ring (1) matches the prosthesis to the physiological lordosis of the vertebral column, cushioning the multiple stresses occurring during these movements.

**(57) Abrégé**

Cette prothèse comprend deux plaques (1, 2) fixées aux vertèbres correspondantes (L4, L5), et une rotule (3) d'articulation des plaques l'une sur l'autre, son centre de rotation (C), dans un plan antéro-postérieur (OX, OY) est décalé vers l'arrière dans la partie postérieure des plaques, dans un plan transversal (OX, OZ) est situé sensiblement au milieu des plaques, et dans un plan vertical (OY, OZ) est situé sous la plaque (1) de la vertèbre inférieure (L5); cette prothèse comporte de plus un anneau intercalaire d'amortissement (10), en une matière souple, percé d'une ouverture (10a) de passage de la rotule (3) et logé dans l'espace délimité entre les plaques et autour de la rotule. Ce positionnement du centre de courbure (C) évite de contraindre les apophyses articulaires lors des mouvements des corps vertébraux, tandis que l'anneau souple (10) adapte la prothèse à la lordose physiologique du rachis lombaire et permet l'amortissement des contraintes multiples lors des mouvements.

UNIQUEMENT A TITRE D'INFORMATION

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- 1 -

"Prothèse discale intervertébrale"

La présente invention a pour objet une prothèse discale intervertébrale.

Comme on le sait, un disque intervertébral se présente sous la forme d'une lentille biconvexe attachée par ses faces aux surfaces articulaires des corps vertébraux. Il est constitué d'une partie périphérique dure (annulus), formée de lamelles fibreuses concentriques, et d'une partie centrale (nucleus pulposus), gélatineuse et molle, constitué de minces faisceaux fibreux séparés par des espaces remplis d'un tissu muqueux. Un disque intervertébral est un élément déformable permettant tous les mouvements relatifs possibles (6 degrés de liberté) mais qui limite les amplitudes de ces derniers, notamment en torsion, en association avec les ligaments intervertébraux et les butoirs osseux. Le disque intervertébral est une structure viscoélastique d'amortissement, qui participe à la résistance et à la stabilité du rachis verticalisé en état de pesanteur.

Un disque intervertébral peut subir des altérations pour diverses raisons, notamment vieillissement et dégénérescence, pouvant provoquer des hernies discales.

La dégénérescence discale correspond à une destruction fonctionnelle puis anatomique du disque, qui semble résulter de l'effet des contraintes mécaniques sur un disque aux structures en voie de désorganisation. La dégénérescence discale modifie le comportement mécanique du disque et aboutit à une diminution de hauteur de l'espace intersomatique, laquelle entraîne une perturbation de l'ensemble fonctionnel disque-articulaires. Il en résulte une instabilité susceptible de provoquer des conséquences cliniques gênantes, notamment des lombalgies. Ainsi l'instabilité segmentaire entraîne un fonctionnement anormal des articulaires, induisant une réaction arthrosi-

que, source de douleurs et de processus ostéophytiques.

On a donc proposé de remplacer le disque déficient par un disque artificiel, dont de nombreux types de réalisations ont été envisagés. Ainsi certaines prothèses comportent des articulations ne supprimant aucun degré de liberté, alors que d'autres au contraire négligent totalement certains mouvements et n'autorisent au maximum qu'un degré de liberté. Les auteurs des premières prothèses considèrent que le disque artificiel ne doit en aucune manière imposer un mouvement, que la stabilité de l'unité fonctionnelle est assurée par la rétention des freins ligamentaires restants et qu'une articulation non contrainte garantit une liaison os/prothèse durable.

Les auteurs du second type de prothèse estiment physiologiquement inutiles certains degrés de liberté, et rétablissent un degré de liberté considéré comme essentiel. Ainsi on connaît une prothèse formant charnière n'autorisant la rotation qu'autour d'un axe transversal.

Les prothèses articulées peuvent être extrêmement variées et comporter notamment des matériaux présentant une certaine souplesse, ou bien mettre en oeuvre des moyens mécaniques tels que des ressorts.

Toutefois ces réalisations connues ne donnent pas entière satisfaction, par exemple parce que les frottements au niveau de l'articulation restent trop élevés (prothèse décrite dans le brevet FR 2 659 226), ou parce que l'on observe une instabilité de la prothèse en rotation. De plus, la prothèse décrite dans le brevet précité ne permet qu'une inclinaison et une flexion extension limitée à 10 degrés dans tous les plans, valeur faible en regard de la mobilité naturelle d'une vertèbre.

Il est encore actuellement relativement difficile de cerner les indications de l'arthroplastie discale, qui

est proposée notamment pour le traitement des lombalgies et sciatalgies par instabilité, des lombo-sciatiques post-disectomie, et des spondylolisthésis de grade I.

5 En fait, le but de l'implant constitué par la prothèse discale visée par l'invention est triple :

10 a) Etre dimensionné pour pouvoir restaurer une hauteur normale de l'espace intersomatique. En effet, la dégénérescence discale, modifiant le comportement mécanique du disque et aboutissant à une diminution de hauteur de l'espace intersomatique, entraîne une perturbation de l'ensemble fonctionnel disque-articulaires. Cette dimi-
15 nution de hauteur provoque une surcharge mécanique sur les facettes articulaires, arthrogène et source possible de lombalgie. Elle peut entraîner un déplacement vers le haut et en avant de l'articulaire supérieur de la vertèbre inférieure, aboutissant à un rétrécissement du trou de conjugaison, cause possible de sciatalgie.

20 b) Autoriser une mobilité physiologique entre les deux vertèbres instrumentées.

L'instabilité peut être consécutive à la dégénérescence discale ou induite par la chirurgie. Les limites entre mobilité normale et anormale ne sont pas encore définies avec précision. L'instabilité segmentaire en-
25 traîne un fonctionnement anormal des articulaires, induisant comme déjà indiqué une réaction arthrosique.

c) Posséder une stabilité intrinsèque et autoriser un mouvement intersomatique.

30 L'arthroplastie s'adresse à des cas où jusqu'à présent une arthrodèse est indiquée. Elle peut être une alternative intéressante à cette intervention, non dénuée de conséquences sur les étages adjacents. En effet, toutes les arthrodèses lombaires entraînent dans les segments

adjacents une augmentation des contraintes et un déplacement des centres de rotation, pouvant conduire à une hypermobilité.

5 Le suivi à long terme des zones adjacentes aux arthrodèses montre un pincement discal constant à partir de la quinzième année, et surtout un glissement ou un déplacement angulaire dont la fréquence augmente avec le recul. On peut aussi observer une arthrose importante, une hernie discale ou une spondylolyse acquise de cette
10 néocharnière.

La prothèse discale visée par l'invention comprend deux plaques équipées de moyens de fixation aux vertèbres correspondantes, ainsi qu'un dispositif d'articulation des plaques l'une sur l'autre.

15 Conformément à l'invention, le dispositif d'articulation est une rotule dont le centre de rotation, dans un plan antéro-postérieur est décalé vers l'arrière dans la partie postérieure des plaques et du corps vertébral, dans un plan transversal est situé sensiblement au milieu
20 des plaques et du corps vertébral, et dans un plan vertical est situé sous la plaque de la vertèbre inférieure ; cette prothèse comporte de plus un anneau intercalaire d'amortissement, réalisé en une matière souple, percé d'une ouverture de passage de la rotule et dimensionné
25 pour se loger dans l'espace délimité entre les plaques et autour de la rotule en épousant sensiblement le contour des plaques.

Le positionnement du centre de courbure de la rotule tel que défini selon l'invention présente l'avantage d'éviter de contraindre les apophyses articulaires,
30 comme dans les vertèbres naturelles, ce qui n'avait pas été jusqu'à présent obtenu avec les prothèses connues.

De plus la prothèse selon l'invention possède tout

à la fois la résistance mécanique nécessaire et des frottements réduits au niveau de l'articulation, grâce au dimensionnement approprié du système à rotule. En effet le centre de rotation n'est ni trop éloigné de l'articulation, ni trop proche de celle-ci, et permet ainsi de reproduire une mobilité proche de la mobilité naturelle.

D'autres particularités et avantages de l'invention apparaîtront au cours de la description qui va suivre, faite en référence aux dessins annexés qui en illustrent une forme de réalisation à titre d'exemple non limitatif.

La figure 1 est une vue en perspective éclatée d'une paire de vertèbres équipées des éléments constitutifs d'une prothèse discale selon une forme de réalisation de l'invention.

La figure 2 est une vue de dessus de la plaque inférieure de la prothèse discale de la Fig.1.

La figure 3 est une vue en coupe longitudinale suivant 3/3 de la Fig.2 de la prothèse selon l'invention dans une position où les deux plaques sont parallèles.

La figure 4 est une vue en élévation de la prothèse des Fig.1 à 3 dans une position où les deux plaques sont inclinées l'une par rapport à l'autre.

La figure 5 est une vue en coupe longitudinale suivant 5-5 de la Fig.6 d'une seconde forme de réalisation de l'invention.

La figure 6 est une vue de dessus de la prothèse de la Fig.5.

La figure 7 est une vue en élévation longitudinale de la prothèse des Fig.5 et 6 avec ses plaques parallèles.

La figure 8 est une vue similaire à la Fig.7 avec les plaques formant un angle entre elles.

Les figures 9, 10, 11 et 12 sont des vues en pers-

pective de quatre variantes d'exécution de la prothèse selon l'invention.

On voit à la Fig.1 deux vertèbres adjacentes, par exemple les vertèbres lombaires L5 et L4, pouvant être reliées par une prothèse discale. Cette prothèse comprend deux plaques 1 et 2, fixées respectivement à la vertèbre inférieure L5 et à la vertèbre supérieure L4, une articulation à rotule 3 des deux plaques 1 et 2 l'une sur l'autre, et un anneau souple 10 d'amortissement intercalé entre les deux plaques 1 et 2 et traversé par la rotule 3.

Les plaques 1, 2 sont similaires, ont des dimensions sensiblement égales à celles des vertèbres L5, L4 (ces vertèbres pouvant être situées à d'autres étages que L5-L4, y compris des étages non lombaires) et épousent approximativement le contour des surfaces articulaires associées. Chaque plaque 1, 2 présente ainsi un bord curviligne 4, sensiblement elliptique ou ovale, et un bord rectiligne 5, destiné à être contigu au canal rachidien, reliant les deux extrémités tronquées de l'ellipse 4. D'autre part chaque plaque 1, 2 est percée, dans sa partie centrale, d'un trou traversant 6 dans lequel est insérée une pastille 7, 8 respective, ayant un corps dimensionné pour pouvoir s'engager dans le trou 6 correspondant. Ce dernier peut être avantageusement conique, de même que les bases complémentaires des pastilles 7, 8, qui peuvent ainsi être solidarisées de manière amovible avec les plaques ou plateaux correspondant 1, 2.

Les pastilles 7, 8 constituent ensemble l'articulation 3 à rotule. La première pastille 7, insérée dans la plaque inférieure 1, présente une surface sphérique convexe 9, située en saillie par rapport à la face correspondante de la plaque 1, tandis que sa surface opposée 11, plane, affleure la face opposée, tournée vers

l'extérieur de la plaque 1. La pastille 8 de la plaque supérieure 2 fait également saillie de sa face tournée vers la plaque 1, et présente une surface sphérique concave 12. Le rayon de courbure de cette dernière est égal à celui (r) de la surface sphérique 9, afin de pouvoir glisser sur celle-ci en formant une articulation à rotule. La face opposée 13 de la pastille 8 est plane et affleure la face extérieure de la plaque 2.

Le centre de courbure ou de rotation C de la rotule 3, distant des surfaces 9 et 12 du rayon de courbure r , est localisé de la manière suivante :

- ce centre C est, dans un plan antéro-postérieur (OX, OY), décalé vers l'arrière dans la partie postérieure des plaques 1, 2 et des corps vertébraux;

- dans un plan transversal (OX, OZ), le centre de rotation C est situé sensiblement au milieu des plaques 1, 2 et des corps vertébraux;

- et dans un plan vertical (OY, OZ), le centre C est situé juste sous la plaque 1 recouvrant la face supérieure de la vertèbre inférieure, par exemple L5 dans l'exemple illustré à la Fig.1.

Ce positionnement du centre C correspond à un rayon de courbure r compris approximativement entre la hauteur de la prothèse quand les plaques 1, 2 sont parallèles, et la moitié de cette hauteur.

En pratique le centre de rotation C peut être situé, au-dessous de la surface inférieure S1 de la plaque 1 (Fig.3), à une distance d_1 comprise entre 0mm - c'est-à-dire être sur la surface S1 elle-même - et environ 5mm selon le cas.

D'autre part, le centre de rotation C est placé à partir du milieu M du côté rectiligne 5 de la plaque 1, contigu au canal rachidien, à une distance du côté 5

comprise entre environ $1/3$ et la moitié de la largeur L de la plaque 1 à partir du milieu M : sur la Fig.3 le centre C est donc situé sensiblement entre la distance $d2 = 1/3.L$ et la distance $d3 = 1/2.L$.

5 A titre d'exemple numérique non limitatif $d2=4\text{mm}$, $d3=10\text{mm}$ et $L=20\text{mm}$, de sorte que C se trouve dans une zone de 6mm de largeur environ.

10 La prothèse comporte de plus un anneau intercalaire d'amortissement 10, réalisé en une matière souple appropriée, percé d'une ouverture 10a de passage de la rotule 3. L'anneau souple 10 est dimensionné pour pouvoir être logé dans l'espace intercalaire délimité entre les plaques 1, 2 et autour de la rotule 3, en épousant sensiblement le contour des plaques.

15 A l'état libre non comprimé (Fig.1), l'anneau souple 10 a une épaisseur variable de sa partie antérieure à sa partie postérieure. Sa partie antérieure a une épaisseur maximum H , qui décroît régulièrement, de part et d'autre du centre du bord de cette partie antérieure, jusqu'à la partie postérieure de l'anneau 10, dont l'épaisseur h est ainsi nettement inférieure à H . L'anneau 10 se présente donc sous la forme d'une pièce asymétrique dont les faces opposées sont inclinées l'une par rapport à l'autre, en se rapprochant vers la partie postérieure.

20 Chaque plaque 1, 2 comporte, sur sa face de laquelle fait saillie la pastille correspondante 7, 8, une surépaisseur annulaire centrale 14, 15. Cette dernière est contiguë à la pastille associée 7, 8 qu'elle entoure en formant un renfort, venu de matière avec le reste de la plaque. De préférence, comme représenté, les renforts 14 et 15 ont une surface conique, dont l'épaisseur décroît à partir de la pastille 7, 8.

30 Dans chaque plaque 1, 2 sont ménagés un ensemble

de trous 16, convenablement répartis le long des bords de la plaque. Ces trous 16 sont agencés pour recevoir des picots 17, fixés dans la plaque 1, 2 par tout moyen convenable, tel que vissage de leur base cylindrique 17a.

5 Leurs pointes 17b, impactées dans l'os sous-chondral des plateaux vertébraux, assurent la fixation des plaques 1, 2 aux vertèbres telles que L5 L4, L5...

Les pastilles 7, 8 formant l'articulation en rotule 3 sont de faibles dimensions par rapport à celles des plaques 1, 2, et sont de manière générale choisies en un matériau présentant les meilleures caractéristiques tribologiques possibles (caractéristiques mécaniques : statiques, dynamiques et résistance à l'usure), et bien entendu biostable. Leur coefficient de frottement doit

10 être faible et leur durée de vie, ainsi que celle des plaques 1, 2, très élevée (par exemple 40 ans).

Ces pastilles 7, 8 peuvent être réalisées en un matériau approprié tel qu'une céramique notamment un oxyde fritté tel qu'alumine ou zircone, une pierre de synthèse,

20 un alliage métallique avec traitement de surface (dépôt de diamant etc).

L'anneau souple 10 d'amortissement est, de préférence, avantageusement constitué en un élastomère de

25 dureté appropriée.

Les plateaux 1, 2 sont prévus en nombre standard, adaptés à tous les morphotypes possibles des corps vertébraux. Les rotules 3 sont par contre en nombre supérieur, adaptées à la morphologie de chaque individu et de chaque

30 étage vertébral. On peut ainsi réaliser une gamme de pièces (plaques 1, 2, rotules 3, anneaux souples 10) adaptées à toutes les hauteurs discales des patients et permettant des combinaisons en nombre infini, adaptées à

chaque cas particulier.

Outre les avantages techniques déjà mentionnés, la prothèse discale selon l'invention présente les avantages suivants .

5 Grâce au dimensionnement approprié de la rotule 3 et à la position de son centre d'articulation C, définis ci-dessus, les surfaces en frottement sont réduites et le frottement provoqué par le basculement des plaques 1, 2 l'une par rapport à l'autre (Fig.4) reste faible. Il en
10 résulte une usure réduite des pastilles 7, 8. Par ailleurs les surfaces 9, 12 de l'articulation ont cependant un rayon de courbure suffisant pour ne pas entraîner une instabilité excessive de la prothèse, tout en lui assurant une mobilité tridimensionnelle convenable, pratiquement
15 identique à celle des vertèbres naturelles.

Durant les mouvements tridimensionnels des plaques 1, 2 et des vertèbres correspondantes, l'anneau souple 10 assure une fonction d'amortissement des contraintes multiples qui limite les mouvements, les faces opposées de
20 l'anneau 10 restant toujours en contact avec les faces correspondantes des plaques 1. La variation de la hauteur, ou de l'épaisseur de l'anneau 10 de l'avant vers l'arrière présente l'avantage de l'adapter à la lordose physiologique du rachis lombaire. Le rapport H/h s'adapte ainsi à la
25 statique rachidienne de profil, en fonction de l'étage discal concerné. L'inclinaison des faces de l'anneau 10 l'une sur l'autre peut varier en fonction de l'étage et de la morphologie du patient. A titre d'exemple elle peut atteindre 15° en L5/S1.

30 Il convient par ailleurs d'observer que le fait que l'épaisseur de la partie antérieure de l'anneau 10 soit supérieure à celle de sa partie postérieure permet une mise en jeu plus précoce du matériau souple consti-

tutif de cet anneau. Ceci entraîne donc la production d'un effet amortisseur dès l'apparition d'un mouvement des corps vertébraux associés à la prothèse. D'autre part, le choix convenable d'un matériau souple pour l'anneau 10, permet l'obtention d'une raideur optimale pour reproduire les pentes des rotations d'un disque sain dans les diverses sollicitations. Finalement, la prothèse selon l'invention permet d'obtenir une raideur et un amortissement très proches ou même identiques à ceux d'un disque naturel.

La mise en place par le chirurgien de la prothèse qui vient d'être décrite se fait que la manière suivante.

Tout d'abord le chirurgien place sur la vertèbre inférieure, par exemple L5, la plaque correspondante 1, la centre convenablement par rapport au corps vertébral, et la fixe par enfoncement des picots 17 dans la vertèbre.

Ensuite le chirurgien met en place sur la vertèbre supérieure, par exemple L4, la plaque supérieure 2, en la positionnant convenablement par rapport à la plaque inférieure 1.

Le chirurgien dispose ensuite entre les plaques 1, 2 un "sandwich" composite constitué par l'assemblage de l'anneau souple 10 et de la rotule 3, formée par les pastilles 7, 8. Il place cet assemblage dans la zone centrale entre les plaques 1, 2, avec les pastilles 7, 8 en regard des trous coniques 6, puis relâche la distraction imposée jusque là aux corps vertébraux recevant les plaques 1, 2. Il en résulte une impaction qui provoque l'entrée des bases coniques des pastilles 7, 8 dans les trous 6, et leur solidarisation à force avec les plaques 1, 2.

Les valeurs des amplitudes angulaires des mouvements possibles avec la prothèse selon l'invention sont

proches des amplitudes ci-dessous d'un disque sain :

	<u>L4/L5</u>	<u>L5/S1</u>
- Flexion/extension	24°	18°
5 - Inclinaison	14°	≤14°
- Rotation axiale	4°	4°

La prothèse selon l'invention garantit par sa solidité la restauration de l'espace intersomatique de hauteur H, tout en présentant une stabilité intrinsèque, c'est-à-dire n'autorisant pas une mobilité non physiologique, surtout en translation.

Les matériaux susceptibles d'être utilisés pour la constitution de la prothèse sont bien entendu biocompatibles et doivent être biologiquement neutres, c'est-à-dire non toxiques, insensibles à la corrosion. De plus ils ne doivent pas être pro-inflammatoires, leurs qualités mécaniques et biologiques ne devant pas être altérées par le mode de stérilisation choisi. A titre d'exemple les plaques 1, 2 peuvent être en acier inoxydable, stellite titane ou alliage de titane.

L'alliage de titane présente l'avantage de posséder des caractéristiques radiologiques et magnétiques avantageuses pour le suivi iconographique de la pathologie rachidienne, ainsi qu'une excellente biotolérance et des caractéristiques mécaniques élevées.

Dans la seconde forme de réalisation de l'invention, illustrée aux Fig.5 à 8, chaque pastille 21 et 22 est logée dans une cuvette respective 23, 24 de réception formée dans la plaque support 25, 26 associée. Les pastilles 21, 22 font partiellement saillie de leurs cuvettes 23, 24 de logement, dans lesquelles elles sont montées librement, et non à force. Autour de chaque cuvette et de

chaque pastille, la surépaisseur annulaire 29, 31 est conique et a une hauteur au sommet h_1 sensiblement égale à l'épaisseur d de la plaque 25, 26.

5 Les pastilles 21, 22 sont coniques, de même que leurs cuvettes de réception 23, 24, et ont un angle de conicité de 1 à 7° environ, et de préférence de 5°.

10 Par ailleurs la prothèse illustrée aux Fig.5 à 8 est similaire à celle des Fig.1 à 4, notamment pour le positionnement du centre de rotation C. L'anneau souple d'amortissement 10 n'a toutefois pas été représenté.

15 L'agencement de cuvettes 23, 24 de réception des pastilles 21, 22 dont les dimensions extérieures correspondent aux dimensions intérieures des cuvettes, dans lesquelles elles ne sont pas fixées et dont elles peuvent être aisément enlevées si nécessaire après un certain temps, sans devoir désolidariser les plaques 25, 26 des vertèbres et les remplacer, présente un avantage appréciable. En effet elle permet d'éviter aux plaques une flexibilité locale au niveau des trous traversants 6 de la réalisation précédente, flexibilité qui n'est pas souhaitable en raison des efforts localisés de serrage auxquels sont soumis les pastilles.

25 Bien entendu celles-ci peuvent en variante être de forme cylindrique, ainsi que les parois des cuvettes correspondantes. Mais cette géométrie ne facilite pas la pose et ultérieurement la dépose éventuelle des pastilles. On a en effet constaté qu'il pouvait se produire une adhésion appréciable des parois des pastilles aux parois des cuvettes, de nature à gêner leur dépose.

30 C'est la raison pour laquelle la légère conicité des pastilles 21, 22 et de leurs cuvettes 23, 24 a été avantageusement prévue, car elle évite cet inconvénient.

Les efforts exercés par le corps du patient sur

les plaques 25, 26 sont réduits du fait de la présence des fonds 27, 28, d'épaisseur e suffisante, par exemple les $3/4$ de l'épaisseur d de chaque plaque ou même cete valeur d . Ainsi les plaques ne présentent aucune faiblesse mécanique locale à la flexion.

Le renfort ou surépaisseur annulaire 29, 31 de chaque plaque 25, 26 accroît par ailleurs la surface des faces en contact entre les parois coniques des cuvettes 23, 24 et des pastilles 21, 22, grâce à l'augmentation de leur hauteur par rapport aux surépaisseurs 14, 15 de la réalisation précédente. Cette augmentation est en effet nécessitée par l'aménagement des fonds 27, 28.

Une telle disposition permet de réaliser une prothèse dont la hauteur totale peut être adaptée à la hauteur désirée par le chirurgien, après consultation des radiographies du système rachidien local de l'opéré.

Pour obtenir la hauteur totale à conférer à la prothèse, le chirurgien dispose d'un jeu de plusieurs rotules 21, 22 dont la hauteur est progressivement croissante, par exemple 11, 13 et 15 centimètres. Pour chacun de ces jeux, le rayon de courbure des faces en contact 9, 12 formant la rotule est adapté pour qu'il soit compris approximativement entre la hauteur H_1 de la prothèse lorsque les plaques 25, 26 sont parallèles entre elles (comme représentées à la Fig.7), et la moitié de cette hauteur.

La Fig.8 illustre la position respective des plaques 25, 26 dans leur ouverture angulaire maximum A, par exemple 32° environ.

Les Fig.9 à 12 illustrent diverses variantes de réalisation possibles des moyens de fixation des plaques ou plateaux aux corps vertébraux, en remplacement des picots 17. Ainsi la Fig.9 montre des plateaux 32, 33 dont

la surface 34 tournée vers les vertèbres est moletée, la Fig.10 montre des plateaux 35, 36 à surface ondulée 37, la Fig.11 montre des plateaux 38, 39 comportant des surfaces bombées 41.

5 La Fig.12 montre des plateaux 42, 43 dont les surfaces 44 d'appui aux corps vertébraux ont subi un traitement adapté : fixation d'un tissu métallique de manière connue en soi, projection d'un métal ou d'une

10 céramique, ou revêtement de collage.
Ce traitement de surface peut du reste être combiné aux variantes des Fig.9 à 11 pour être appliqué aux surfaces 34, 37, 41.

Les picots 17 peuvent aussi être remplacés par des vis ou plots.

15 En revanche, la fixation par ciment (méthylméthacrylate) n'est pas envisageable, compte tenu de la proximité des éléments nerveux et du dégagement de chaleur lors de la polymérisation. Pour des étages non lombaires, l'anneau souple 10 peut ne pas présenter l'asymétrie

20 décrite et donc avoir une épaisseur uniforme.

Il convient d'observer que la prothèse discale selon l'invention ne comporte pas de pièce libre, contrairement à certaines prothèses discales connues. Ceci présente l'avantage d'éliminer tout risque d'éjection

25 d'une telle pièce libre contre l'aorte ou vers le canal rachidien.

REVENDECATIONS

1. Prothèse discale intervertébrale, comprenant deux plaques (1, 2) équipées de moyens de fixation aux vertèbres correspondantes (L4, L5), et un dispositif (7, 8) d'articulation des plaques l'une sur l'autre, caractérisée en ce que le dispositif d'articulation est une rotule (3) dont le centre de rotation (C), dans un plan antéro-postérieur (OX, OY) est décalé vers l'arrière dans la partie postérieure des plaques et du corps vertébral, dans un plan transversal (OX, OZ) est situé sensiblement au milieu des plaques et du corps vertébral, et dans un plan vertical (OY, OZ) est situé sous la plaque (1) de la vertèbre inférieure (L5), et en ce que cette prothèse comporte de plus un anneau intercalaire d'amortissement (10), réalisé en une matière souple, percé d'une ouverture (10a) de passage de la rotule (3) et dimensionné pour se loger dans l'espace délimité entre les plaques et autour de la rotule en épousant sensiblement le contour des plaques.

2. Prothèse selon la revendication 1, caractérisée en ce que l'articulation à rotule (3) est constituée par une première pastille (7) à surface sphérique convexe (9) et une seconde pastille (8) à surface sphérique concave (12) recevant la surface sphérique convexe, ces deux surfaces sphériques ayant le même rayon de courbure (r) et les pastilles étant montées dans les parties centrales des plaques respectives (1, 2), sur les faces en vis-à-vis desquelles elles font saillie.

3. Prothèse selon la revendication 2, caractérisée en ce que, chaque plaque (1, 2 ; 25, 26) ayant un côté rectiligne (5) destiné à être positionné près du canal rachidien et un contour (4) complémentaire sensiblement ovale, ou elliptique, la pastille (7; 22) à surface

sphérique convexe (9) est montée dans la plaque (1; 26) de la vertèbre inférieure et son centre de rotation (C) est situé, à partir du milieu (M) du côté rectiligne de la plaque contigu au canal rachidien, à une distance dudit côté comprise entre environ un tiers (d2) et la moitié (d3) de la largeur (L) de la plaque à partir dudit milieu et sous la plaque de la vertèbre inférieure, le centre de rotation est situé à une distance (d1) de la plaque comprise entre 0 et environ 5mm.

4. Prothèse selon la revendication 2 ou 3, caractérisée en ce que chaque plaque (1,2; 25,26) comporte, sur la face de laquelle fait saillie la pastille (7, 8; 21,22), une surépaisseur annulaire centrale (14,15; 29,31), contiguë à la pastille qu'elle entoure en formant renfort.

5. Prothèse selon la revendication 4, caractérisée en ce que le renfort (14,15; 29,31) a une surface conique, dont l'épaisseur (h1) décroît à partir de la pastille (7, 8).

6. Prothèse selon l'une des revendications 2 à 5, caractérisée en ce que les pastilles (7,8; 21,22) ont une base conique adaptée à des trous coniques conjugués ménagés dans les plaques (1,2; 25,26).

7. Prothèse selon l'une des revendications 1 à 6, caractérisée en ce que les moyens de fixation des plaques (1,2; 25,26...) aux vertèbres (L5, L4) comprennent des picots coniques (17) vissés dans des trous (16) formés dans les plaques et convenablement répartis sur celles-ci, ou un moletage (34), ou une surface ondulée (37), ou une surface bombée (41).

8. Prothèse selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la fixation des plaques (42, 43) aux vertèbres est assurée par un tissu métallique

(44), un métal ou une céramique projeté(e) sur la surface de la plaque en regard de la vertèbre, ou par collage, ou encore par combinaison de l'un de ces moyens avec, soit une surface moletée (34) ou ondulée (37) ou bombée (41).

5 9. Prothèse selon l'une des revendications 1 à 8, caractérisée en ce que les plaques (1,2; 25,26...) ont des dimensions identiques et sensiblement égales à celles d'une vertèbre, notamment lombaire.

10 10. Prothèse selon l'une des revendications 1 à 9, caractérisée en ce que l'anneau souple (10) d'amortissement a une partie antérieure d'épaisseur maximum (H), supérieure à celle (h) de sa partie postérieure, ladite épaisseur (H) décroissant régulièrement du centre du bord de la partie antérieure à la partie postérieure, et les
15 faces opposées de l'anneau (10), à l'état non comprimé, sont corrélativement inclinées l'une par rapport à l'autre.

20 11. Prothèse selon l'une des revendications 1 à 10, caractérisée en ce que les pastilles (7,8; 21,22) de la rotule (3) sont réalisées en l'un des matériaux suivants: céramique notamment oxyde fritté tel qu'alumine ou zircon, pierre de synthèse, alliage métallique avec traitement de surface.

25 12. Prothèse selon l'une des revendications 1 à 11, caractérisée en ce que l'anneau souple (10) est en élastomère de dureté appropriée.

30 13. Prothèse selon l'une des revendications 2 à 12, caractérisée en ce que chaque pastille (21, 22) est logée dans une cuvette (23, 24) de réception formée dans la plaque support (25, 26) dont elle fait partiellement saillie et dans laquelle elle est montée librement.

1/6

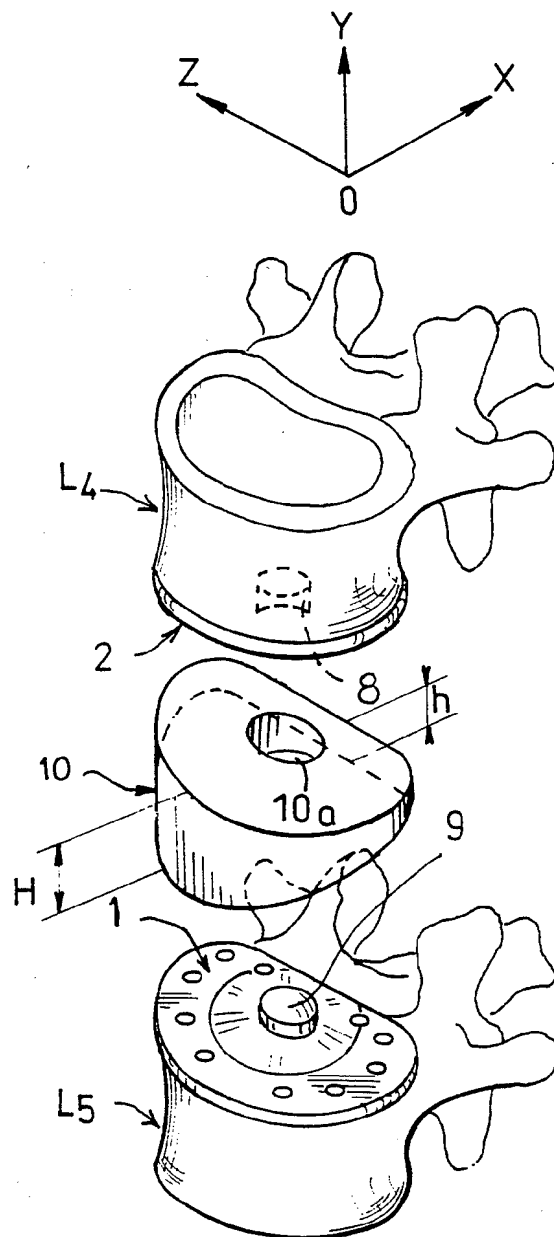


FIG.1

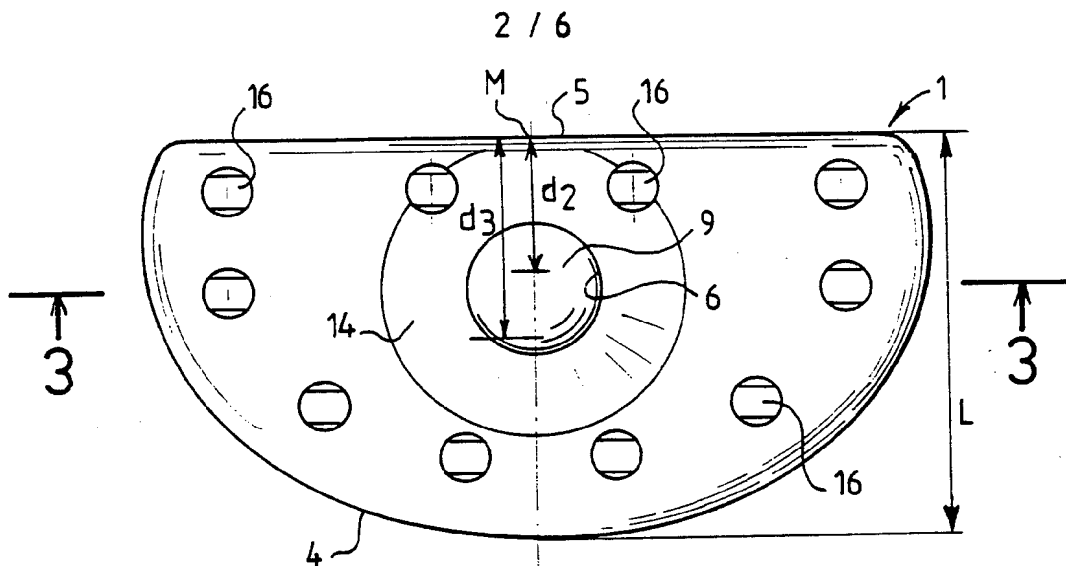


FIG. 2

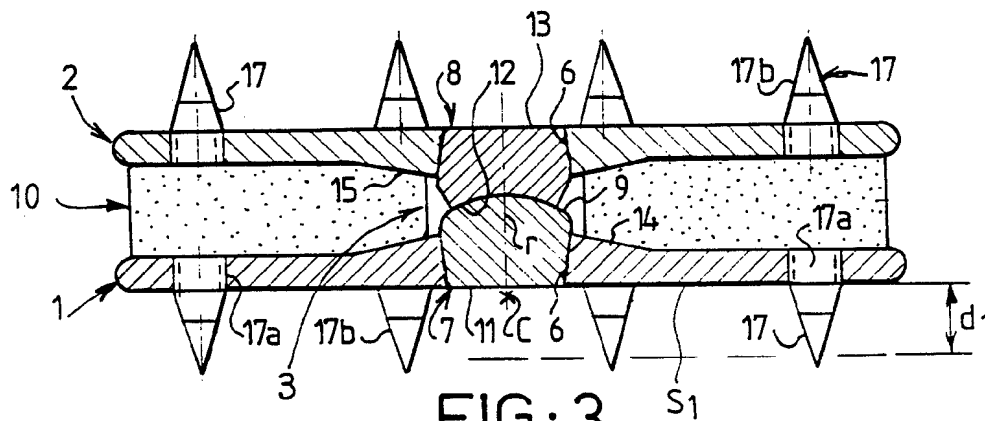


FIG. 3

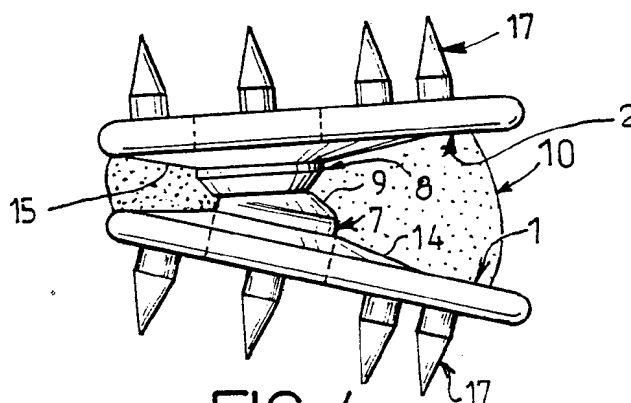


FIG. 4

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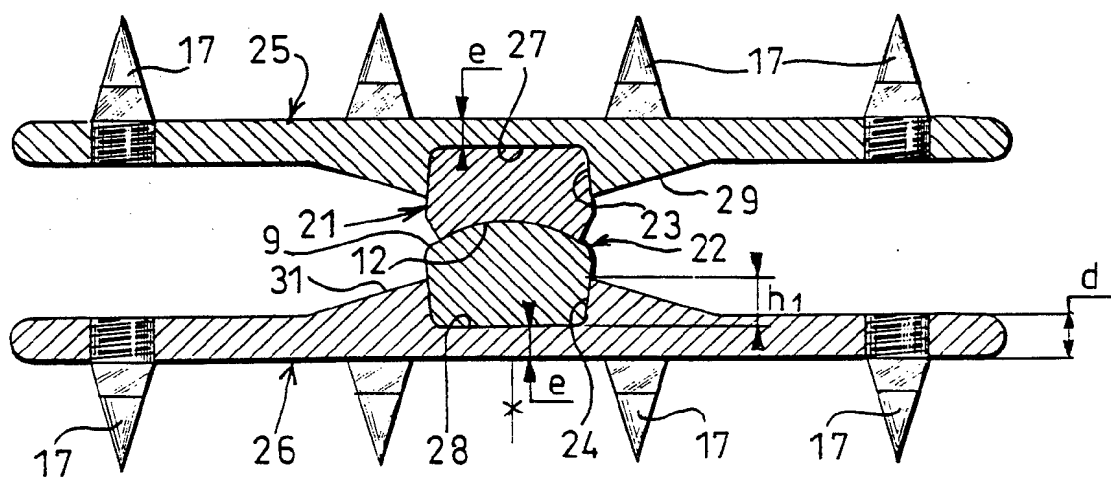


FIG. 5

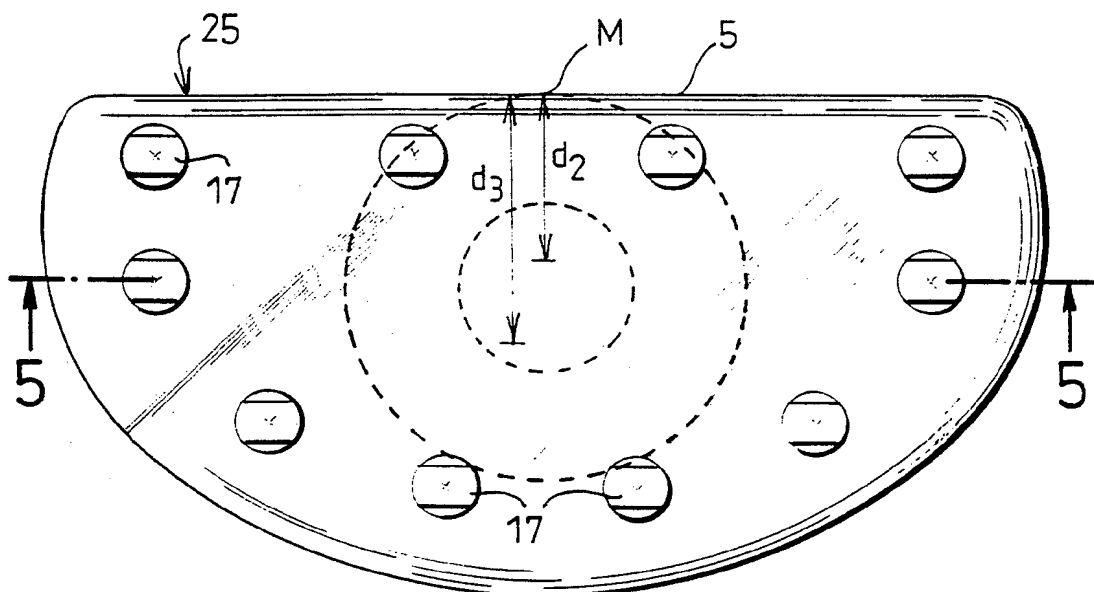


FIG. 6

FIG.7

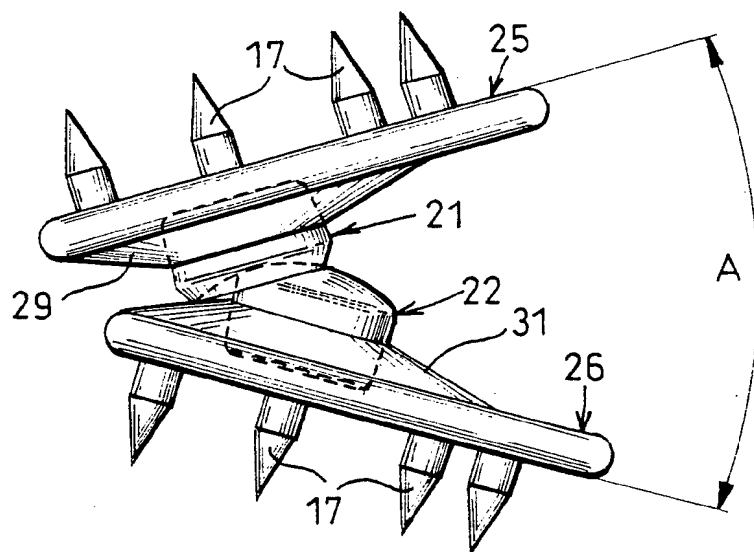
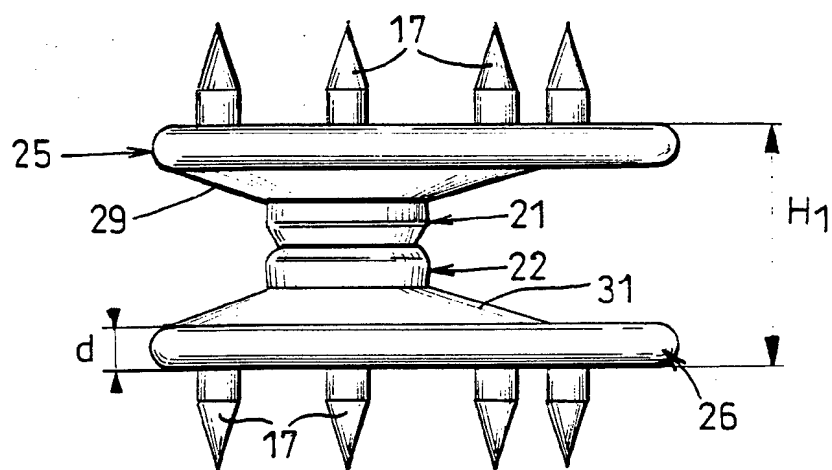


FIG.8

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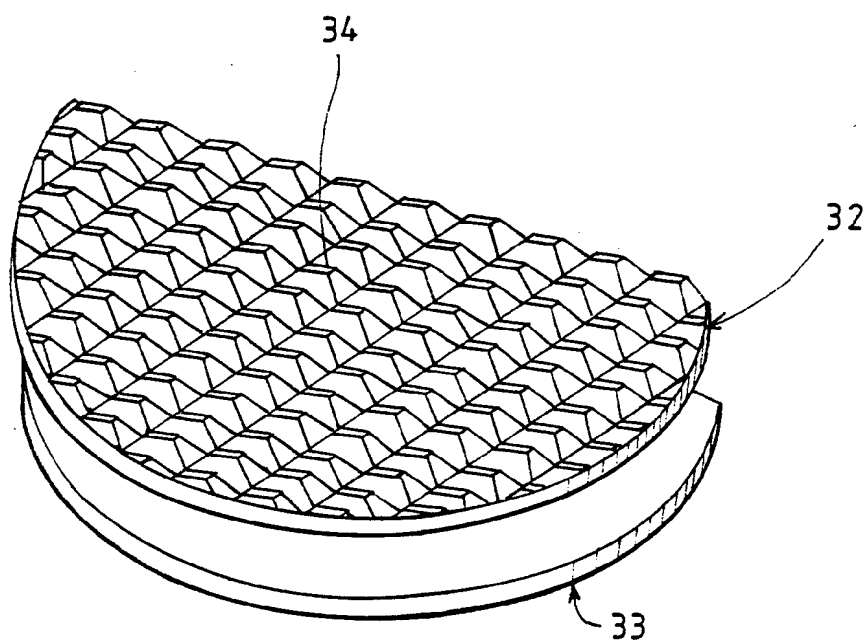


FIG. 9

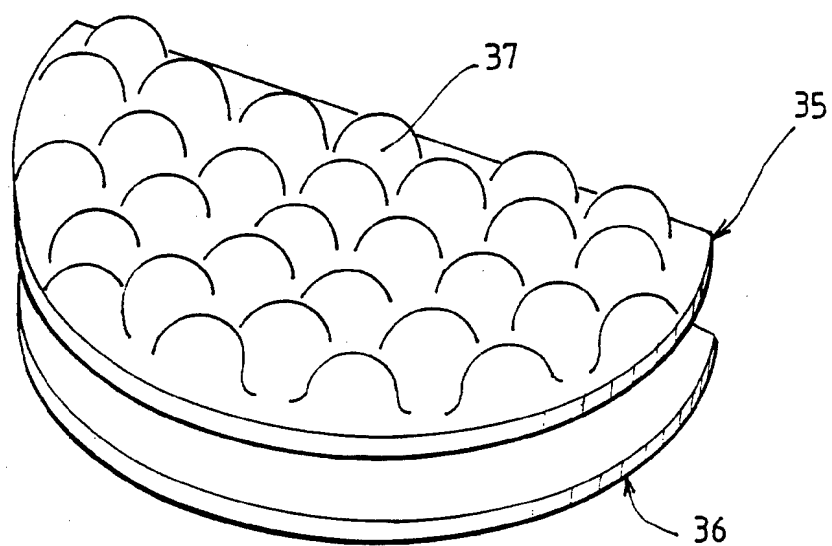


FIG. 10

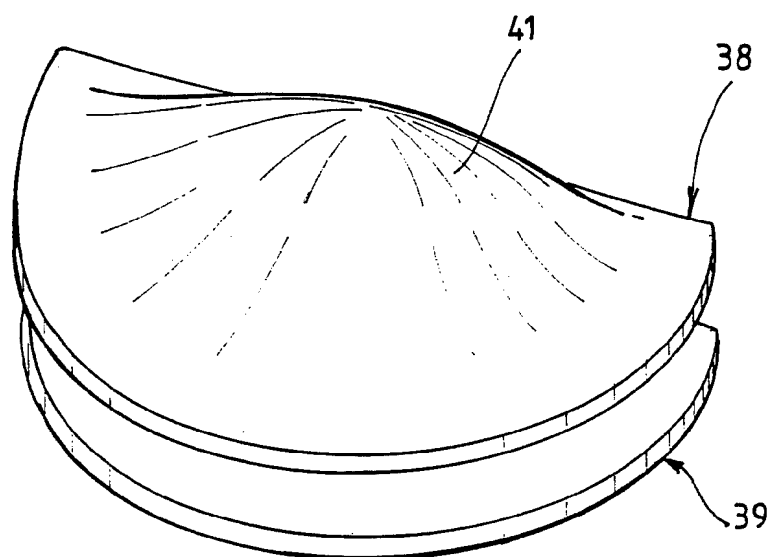


FIG. 11

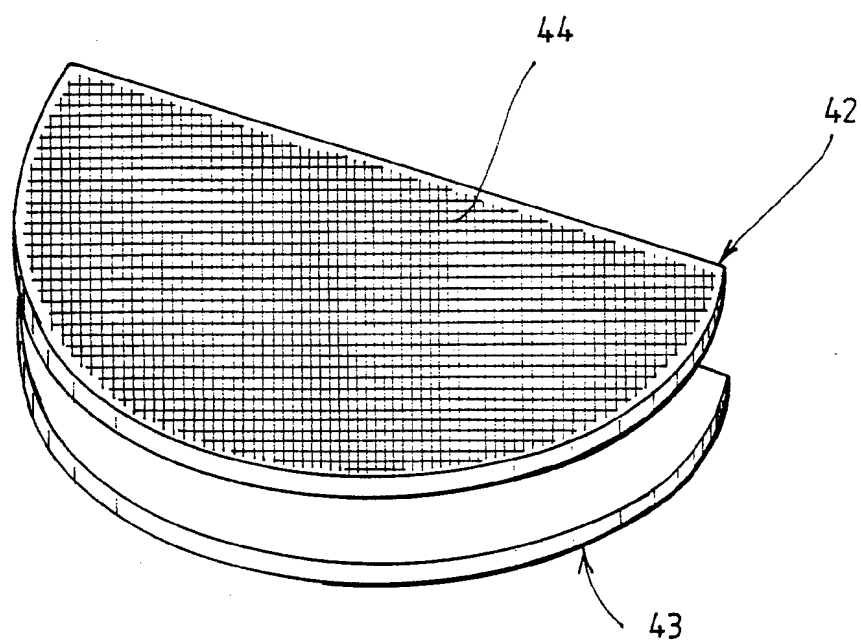


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FR 93/00825

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl.5 A61F2/44; A61L27/00; A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl.5 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4 759 769 (HEDMAN) 26 July 1988	1,9,12
A	see abstract see column 2, line 44 - column 3, line 15; figures 1,2,8	11
Y	DE, A, 2 263 842 (HOFFMANN-DAIMLER) 4 July 1974	1,9,12
A	see page 18, line 23 - page 19, line 25; claim 4; figure 9	2,4,5,11
A	WO, A, 9 113 598 (MARNAY) 19 September 1991 see page 10, line 16 - page 11, line 3; claim 1; figures 1-3 cited in the application	1,2,7,9, 13
A	US, A, 4 932 975 (MAIN) 12 June 1990 see column 2, line 45 - column 3, line 16	1,9,11, 12

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

6 October 1993 (06.10.93)

Date of mailing of the international search report

12 October 1993 (12.10.93)

Name and mailing address of the ISA/

EUROPEAN PATENT OFFICE

Facsimile No.

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Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/FR 93/00825

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	see column 3, line 46 - line 59; figures 1,8,12 ---	
A	US, A, 4 714 469 (KENNA) 22 December 1987 see column 3, line 52 - line 58; figures 1-3 ---	3,7,8
A	WO, A, 9 011 740 (ROBERT BOSCH) 18 October 1990 see claims; figures ---	3,10-12
A	DE, U 8 912 648 (MECRON) 22 November 1990 see claim 1; figures ---	7,8
A	US, A, 4 309 777 (PATIL) 12 January 1982 see column 2, line 7 - line 13; figures 1,4 ---	7,9
A	EP, A, 0 298 235 (SULZER) 11 January 1989 see column 3, line 15 - line 21; figures 1-3 ---	8
A	DE, A, 3 023 353 (SULZER) 9 April 1981 see page 4, line 21 - line 25; figures ---	8

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

FR 9300825
SA 78503

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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RAPPORT DE RECHERCHE INTERNATIONALE

PCT/FR 93/00825

Demande Internationale No

I. CLASSEMENT DE L'INVENTION (si plusieurs symboles de classification sont applicables, les indiquer tous) ⁷		
Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB <div style="display: flex; justify-content: space-between;"> CIB 5 A61F2/44; A61L27/00; A61F2/30 </div>		
II. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE		
Documentation minimale consultée ⁸		
Système de classification	Symboles de classification	
CIB 5	A61F	
Documentation consultée autre que la documentation minimale dans la mesure où de tels documents font partie des domaines sur lesquels la recherche a porté ⁹		
III. DOCUMENTS CONSIDERES COMME PERTINENTS ¹⁰		
Catégorie ^o	Identification des documents cités, avec indication, si nécessaire, ¹² des passages pertinents ¹³	No. des revendications visées ¹⁴
Y A Y A A	US,A,4 759 769 (HEDMAN) 26 Juillet 1988 voir abrégé voir colonne 2, ligne 44 - colonne 3, ligne 15; figures 1,2,8 --- DE,A,2 263 842 (HOFFMANN-DAIMLER) 4 Juillet 1974 voir page 18, ligne 23 - page 19, ligne 25; revendication 4; figure 9 --- WO,A,9 113 598 (MARNAY) 19 Septembre 1991 voir page 10, ligne 16 - page 11, ligne 3; revendication 1; figures 1-3 cité dans la demande --- <div style="text-align: right;">-/--</div>	1,9,12 11 1,9,12 2,4,5,11 1,2,7,9, 13
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> ^o Catégories spéciales de documents cités:¹¹ "A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent "E" document antérieur, mais publié à la date de dépôt international ou après cette date "I" document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée) "O" document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens "P" document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée </div> <div style="width: 45%;"> "T" document ultérieur publié postérieurement à la date de dépôt international ou à la date de priorité et n'appartenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention "X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive "Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier. "&" document qui fait partie de la même famille de brevets </div> </div>		
IV. CERTIFICATION		
Date à laquelle la recherche internationale a été effectivement achevée <div style="text-align: center; font-weight: bold;">06 OCTOBRE 1993</div>		Date d'expédition du présent rapport de recherche internationale <div style="text-align: center; font-weight: bold;">12. 10. 93</div>
Administration chargée de la recherche internationale <div style="text-align: center; font-weight: bold;">OFFICE EUROPEEN DES BREVETS</div>		Signature du fonctionnaire autorisé <div style="text-align: center; font-weight: bold;">KLEIN C.</div>

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Catégorie ^o	Identification des documents cités, ¹⁶ avec indication, si nécessaire des passages pertinents ¹⁷	No. des revendications visées ¹⁸	
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A	US,A,4 714 469 (KENNA) 22 Décembre 1987 voir colonne 3, ligne 52 - ligne 58; figures 1-3 ---	3,7,8	
A	WO,A,9 011 740 (ROBERT BOSCH) 18 Octobre 1990 voir revendications; figures ---	3,10-12	
A	DE,U,8 912 648 (MECRON) 22 Novembre 1990 voir revendication 1; figures ---	7,8	
A	US,A,4 309 777 (PATIL) 12 Janvier 1982 voir colonne 2, ligne 7 - ligne 13; figures 1,4 ---	7,9	
A	EP,A,0 298 235 (SULZER) 11 Janvier 1989 voir colonne 3, ligne 15 - ligne 21; figures 1-3 ---	8	
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**ANNEXE AU RAPPORT DE RECHERCHE INTERNATIONALE
RELATIF A LA DEMANDE INTERNATIONALE NO.**

FR 9300825
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La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche internationale visé ci-dessus.

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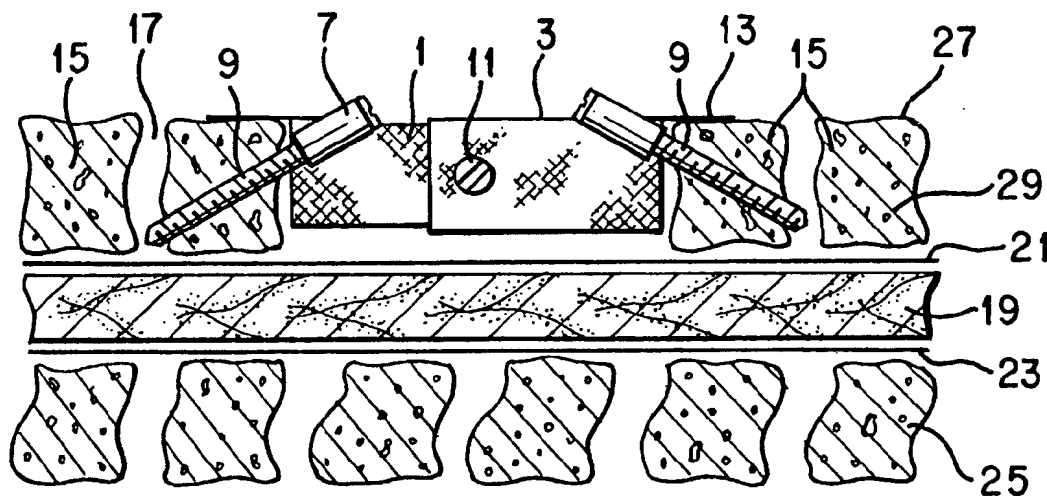
Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 2/44	A1	(11) International Publication Number: WO 94/18913 (43) International Publication Date: 1 September 1994 (01.09.94)
(21) International Application Number: PCT/US94/01484 (22) International Filing Date: 16 February 1994 (16.02.94) (30) Priority Data: 08/018,373 16 February 1993 (16.02.93) US (71)(72) Applicants and Inventors: HENDERSON, Fraser, C. [US/US]; 6705 South Osborne Road, Upper Marlboro, MD 20772 (US). HENDERSON, Rebecca, Sasscer [US/US]; 6705 South Osborne Road, Upper Marlboro, MD 20772 (US). NEWMAN, John, W. [US/US]; 27 Paper Mill Road, Newtown Square, PA 19073 (US). (74) Agent: EILBERG, William, H.; 820 Homestead Road, P.O. Box 7, Jenkintown, PA 19046-0007 (US).		(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: FUSION STABILIZATION CHAMBER



(57) Abstract

A fusion stabilization chamber stabilizes the spine following removal of one or more vertebrae, and facilitates bone growth. The chamber includes two hollow members (1), (3), preferably having slightly trapezoidal cross sections, which slide relative to each other in a telescoping manner. The hollow members preferably have walls made of a metal mesh (5). Barrel vaults (7) attached to the hollow members form guides for screws (9) which can attach the chamber to the vertebrae adjacent the corpectomy site. Because of its adjustability, the chamber can fit a wide variety of corpectomy sites. One can fill the chamber with bone material, which can eventually fuse to the adjacent bone. A pair of stabilizing plates (13) prevents the surgeon from pushing the chamber too far towards the spinal cord. The chamber eliminates the need to maintain a large and costly inventory of screws, and neurosurgeons can learn to use it quickly and easily.

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FUSION STABILIZATION CHAMBER

BACKGROUND OF THE INVENTION

The present invention relates to the field of neurosurgery, and provides a device which facilitates the implantation of bone into the spine following removal of vertebrae, and which also facilitates the fusion of the implanted bone with the surrounding bone. The invention also includes a method of performing spinal surgery, and in particular, of stabilizing the spine following removal of one or more vertebrae.

Cancer or trauma or degenerative changes can cause parts of the human vertebrae to develop outgrowths or ridges that can touch the spinal cord and cause pain and/or paralysis. Neurosurgeons have developed means of treating such conditions, by removing part of the vertebrae, and, where appropriate, replacing the removed bone with something else. The removal of all or part of a vertebra is called a "corpectomy" or a "vertebrectomy". In some cases, one can replace the bone removed by corpectomy with bone taken from another site on the body of the patient; in other cases, one can obtain bone from a "bone bank". Given the right conditions, the new bone material will fuse to the bone surrounding the corpectomy site, and can become for practical purposes a part of the patient's body. To achieve the desired fusion, one must stabilize the spine so that the bone has time to fuse. The fusion process can take from six weeks to six months.

In performing spinal surgery, one can approach the spine either from the front (anterior) or rear (posterior) sides. The posterior approach has the disadvantage that since the vertebrae lie on the anterior side of

the spinal cord, the surgeon must navigate past the spinal cord before reaching the vertebrae, and must take special care not to disturb the spinal cord. Conversely, with the anterior approach, the surgeon does not encounter the spinal cord while en route to the vertebrae. The present invention concerns the anterior approach.

The prior art contains many systems for stabilizing various parts of the spine following surgery. The development of such systems has made it possible to treat certain lesions of the spine aggressively, instead of simply immobilizing them in a brace. The typical external immobilizing device of the prior art comprises the halo vest. The typical internal immobilizing device comprises the Caspar plate, described below.

The Caspar plate system, named after Dr. Wolfhard Caspar, comprises a means for stabilizing the spine after anterior spinal surgery. The Caspar system includes a set of plates which one attaches to the remaining vertebrae surrounding the corpectomy site. In the Caspar procedure, one screws a plate directly onto the spine, the screws approaching within about one or two millimeters of the spinal cord. The Caspar system provides immediate stabilization of the spine following a corpectomy, and in other cases where the spine has become unstable following an accident. The Caspar system also eliminates the need for wearing the very cumbersome halo vest, and eliminates the need to undergo a separate surgical procedure from the rear.

However, the Caspar system also has disadvantages. It requires a large inventory of expensive equipment, including screws and plates of all sizes. The latter expense can represent a formidable obstacle to many medical institutions. Also, one needs to insert the screws through the spine, engaging the posterior cortex. Although one can monitor the

position of the screws with an appropriate real-time viewing apparatus, the procedure carries the potential risk of spinal cord injury or laceration of the vertebral artery. When a competent surgeon performs the procedure, these complications rarely occur, but other complications such as loosening of the screws and persistent instability may develop. Moreover, the difficulty of the procedure discourages many surgeons from even attempting the anterior plating procedure.

The Synthes cervical spine locking plate constitutes another anterior plating system of the prior art. In the Synthes system, one inserts a second screw into the head of the anchor screw, thus creating a second affixation of the plate to the vertebrae. Many regard the Synthes system as easier, safer, and faster to use than the Caspar plate system, because the anchor screw does not penetrate the posterior cortex and because one therefore does not need to monitor the precise position of the screw during insertion. However, the Synthes locking plate has less versatility than the Caspar plate, as it provides the ability to fuse only two to three levels of the cervical spine.

Both the Caspar and Synthes systems also have the disadvantage that they do not work well in patients with osteoporosis, rheumatoid arthritis, ankylosing spondylitis, and other conditions of poor bone growth or metabolic bone disease.

Both the Caspar and Synthes systems have additional disadvantages inherent with the use of screws. First, as mentioned above, screws do become loose. If one uses the screws as the primary means of affixing the stabilizing device to the spine of the patient, loosening of the screws represents a major problem. Moreover, the use of screws presents a technical challenge to the surgeon. Correct screw placement requires experience, as well as a large inventory of expensive equipment, as well

as imaging devices for monitoring the position of such screws. Also, with screw-based systems of the prior art, the surgeon must create a large opening in the patient, so as to view the screw along its shaft. Such an opening creates additional risks to the patient, such as the risk of injury to vascular structure and to nearby nerves.

In addition to the problem of how to stabilize the spine immediately after performing a corpectomy, vertebral surgery poses problems relating to the replacement of the removed bone. Some systems of the prior art require the use of a bone strut to replace the diseased bone segments removed in surgery. This bone grafting material costs a great deal, and sometimes one cannot obtain enough material when performing multiple vertebrectomies. Furthermore, bone graft material, usually taken from cadavers, has typically been sterilized by radiation, a process believed to weaken or destroy the strength and osteoconductive properties of bone. While it is possible to use other means of sterilization, such as ethylene oxide or freeze drying, it usually turns out that the best bone graft material comes from the patient, because the patient's own bone will likely fuse more rapidly than bone obtained elsewhere. Unfortunately, harvesting such bone consumes substantial time, involves substantial pain to the patient, and presents other risks, such as risk of infection at the harvest site, hemorrhage, and peripheral nerve injury.

The present invention overcomes the disadvantages of the prior art systems described above. First, the invention provides a device which surgeons can learn to use very easily, and which they can insert without intraoperative fluoroscopy or other means of accurately monitoring the position of a device within the body. Most neurosurgeons can use the device of the present invention with instruments already in their posses-

sion.

Secondly, the invention provides an adjustable device which can fit a large range of patients. This feature eliminates the need to keep a large inventory of parts in order to accommodate every possible patient.

Thirdly, the device allows one to use the patient's own cancellous bone which one removes during the vertebrectomy, possibly with the addition of further cancellous bone material from an external source. In any event, the invention reduces or eliminates the need to obtain a pelvic bone autograft from the patient.

The device of the present invention also reduces or eliminates the problem of loosening of screws, which can occur with the plating systems of the prior art, and which clearly can cause substantial pain and expense.

SUMMARY OF THE INVENTION

The fusion stabilization chamber of the present invention includes a pair of hollow members, both of which may have a rectangular or slightly trapezoidal cross-section. One of the hollow members slides within the other. Thus, the chamber comprises two telescoping hollow members. Each hollow member includes at least one barrel vault at one end, each barrel vault comprising threaded means for receiving a screw. The barrel vaults are arranged in a mutually oblique manner, such that the screws inserted into the vaults also lie along mutually oblique lines. The hollow members preferably comprise enclosures defined by four walls formed of a metal mesh. The hollow members may also include means for locking the members in a desired position relative to each other.

In using the stabilization chamber described above, the surgeon

first removes the diseased portion of vertebra in the usual manner. The surgeon measures the length of the corpectomy site (the length of the space to be filled), and adjusts the length of the chamber accordingly. One may fasten the locking means so that the telescoping chamber maintains its desired position. Then, the surgeon fills the chamber with bone material, such as bone chips obtained from the corpectomy operation itself, or bone material from other sources, and inserts the chamber into the corpectomy site. The surgeon gently taps the device into place, so that it fills most of the corpectomy site, i.e. the space formerly occupied by the removed vertebra. The chamber does not extend all of the way towards the spinal cord, due to the retaining action of a pair of stabilizing plates.

The surgeon then drills holes in the surrounding bone, using the barrel vaults as guides for the drill bit. The surgeon then inserts the screws through the barrel vaults and fastens them to the bone. Due to the orientation of the barrel vaults, the screws lie along mutually oblique paths, reducing the likelihood that the device will become dislodged.

In an alternative embodiment, one can provide threaded holes in the stabilizing plates also, so that additional screws can pass directly through the stabilizing plates and into the surrounding bone.

The present invention therefore has the primary object of providing an improved method and apparatus for performing spinal surgery, and in particular, for stabilizing the spine following removal of one or more vertebrae.

The invention has the further object of providing a device which promotes bone fusion in addition to providing stabilization of the spine.

The invention has the further object of simplifying the surgical process of stabilizing the spine after performing a corpectomy.

The invention has the further object of reducing the cost and complexity of the equipment needed to practice spinal surgery.

The invention has the further object of reducing the time required for a surgeon to learn to stabilize the spine following a corpectomy.

Persons skilled in the art will recognize other objects and advantages of the invention, from a reading of the following brief description of the drawings, the detailed description of the invention, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 provides a side elevational view of the fusion stabilization chamber of the present invention.

Figure 2 shows an end view of the stabilization chamber of the present invention.

Figure 3 provides a perspective view of the fusion stabilization chamber.

Figure 4 shows a top view of the stabilization chamber.

Figure 5 provides a diagrammatic view showing the fusion stabilization chamber inserted into a corpectomy site.

Figure 6 provides a perspective view of an alternative embodiment of the invention, wherein additional screws pass directly through the stabilizing plates.

DETAILED DESCRIPTION OF THE INVENTION

Figures 1-4 show the physical structure of the fusion stabilization chamber of the present invention. The chamber includes first hollow member 1 and second hollow member 3. Both hollow members have a slightly trapezoidal cross-section, as illustrated in the end view of Figure 2. Figure 2 exaggerates the trapezoidal shape of the cross-section; in practice, the width of the member might increase by one millimeter for each 15 mm of depth, but one could use other dimensions. Thus, by "slightly trapezoidal", one means that the members are nearly rectangular in cross-section, except for the variation in width described above. The trapezoidal cross-section helps to maintain the chamber in position within the corpectomy site. One inserts the narrower portion of the hollow member into the body cavity first, with the wider portion oriented towards the outside. Thus, the chamber tends to become wedged in its place within the corpectomy site; once pushed in, it becomes difficult to pull out. Although the preferred embodiment includes the trapezoidal cross-section, one can also form the chamber with a perfectly rectangular cross-section, within the scope of the invention.

The first hollow member 1 slides within the second hollow member 3. The members 1 and 3 preferably have walls formed of metal mesh 5. One prefers walls having openings which permit bone growth from the adjacent vertebrae, through the interior of the chamber. However, the walls can have a different construction. They can even comprise solid metal, as bone can fuse to metal. In the latter case, the chamber could be empty.

In the preferred embodiment, the chamber has two pairs of barrel vaults 7, arranged at the opposite ends of the hollow members. One can vary the number of barrel vaults, within the scope of the invention. The

barrel vaults comprise threaded cylinders through which screws 9 pass. Figure 1 shows that the screws form an angle of about 30° relative to the top longitudinal axis of the chamber. Figure 4 shows that the screws also form an angle of about 10° relative to the sides of the chamber. One can vary these angles; one should not consider the invention limited to particular angles. In general, one selects angles which enable the screws to pass through the greatest possible thickness of bone, above and below the corpectomy site, and to provide an angle which, from the perspective of the surgeon, facilitates insertion of the screws without the need to make a larger or additional incision.

As shown in the Figures, the barrel vaults comprise mutually oblique members. The screws become self-locking in the barrel vaults. One can also provide an adjustable hexagonal head screwdriver to facilitate tightening of the screws from any angle.

Locking screw 11 holds the first and second hollow members in place. The locking screw thus permits adjustment of the size of the chamber. One slides the hollow members until the chamber has the desired length, and then fixes the selected length by tightening the locking screw.

Figure 5 provides a diagram of the fusion stabilization chamber inserted into a corpectomy site. The figure shows vertebrae 15, the spaces 17 between adjacent vertebrae representing intervertebral discs. Each vertebra includes an outer bony layer, or cortex 27, which surrounds cancellous material 29 inside. Figure 5 also shows spinal cord 19, and the structures adjoining the spinal cord, including the posterior longitudinal ligament 21, the ligamentum flavum 23, and the posterior spinous processes 25. As shown in the figure, one has removed several vertebrae, and has inserted the chamber into the resulting empty space.

Stabilizing plates 13 extend from both hollow members, as shown in

the Figures. The stabilizing plates serve several purposes. First, as illustrated in Figure 5, the stabilizing plates keep the chamber at an appropriate depth, preventing the chamber from touching spinal cord 19 or the ligaments surrounding it. By making the depth of the chamber less than the depth of the adjacent vertebrae, one prevents the chamber from coming too close to the spinal cord.

Secondly, the stabilizing plates tend to distribute the bending loads experienced by the chamber, and divert part of these loads away from the screws. As the vertebrae flex back and forth, the stabilizing plates tend to oppose some of the vertebral movement, and absorb some of the tension, thereby tending to prevent the screws from loosening or breaking.

Thirdly, the stabilizing plates help to rigidify the joints formed between the ends of the chamber and the respective adjacent vertebrae. Keeping these joints rigid facilitates the growth of blood vessels from the adjacent vertebrae, through the holes in the chamber walls, and into the bone material within the chamber.

Figure 6 shows, in a perspective view, an alternative embodiment wherein a third screw passes through a threaded hole in each stabilizing plate, in addition to the pair of screws inserted through the associated barrel vaults. Figure 6 shows additional screw 10 inserted through the stabilizing plate on the right-hand side. The figure does not show the corresponding additional screw on the other side, in order to show the hole in the stabilizing plate, but in practice a similar additional screw 10 would normally be provided. However, one should consider each screw as optional, since it is possible to affix the chamber to the adjacent bone using fewer than all of the available screws.

One would use the embodiment of Figure 6 in cases where the bone has become weakened. In rare cases, one might even attach the chamber only with the stabilizing plate screws, without any barrel vault screws. In all of the embodiments wherein one provides a threaded hole in the stabilizing plate, the holes should have low "profiles", so that the material defining the plate does not project significantly beyond the plane of the plate.

In using the chamber of the present invention, the surgeon begins by performing a corpectomy in the conventional manner. Immediately after removal of one or more vertebrae, the surgeon measures the length of the corpectomy site with calipers, and adjusts the length of the chamber to make it conform to the length of the corpectomy site. One adjusts the length of the chamber by pulling the hollow members 1 and 3 away from each other or pushing them together, as needed. Then one tightens the locking screw 11 to fix the length (and thus the volume) of the chamber.

Next, the surgeon fills the chamber with bone. The bone can comprise bone chips obtained from the vertebrae removed in the corpectomy procedure, or it can comprise cancellous bone obtained from another site. One might also use a biocompatible osteogenic polymer.

In a variation of the latter step, the surgeon may place bone chips, obtained from the corpectomy, into the chamber, while the corpectomy progresses. However, in this case, one would still need to adjust the chamber to fit the corpectomy site, and one would also need to insure that the bone has substantially filled the volume of the chamber after adjustment of the size of the chamber.

The surgeon then inserts the bone-filled chamber into the corpectomy site, and gently taps it into place, such that the stabilization plates 13 come to rest on the vertebrae immediately adjacent to the corpectomy

site. The chamber should fit tightly within the corpectomy site. One may take a lateral spine X-ray to insure that the chamber has seated itself properly in the corpectomy site.

Next, the surgeon drills holes into the adjacent vertebrae, using an appropriate drill, such as a 2mm twist drill. The barrel vaults 7 form guides for the drill bit, and thereby determine the direction of the holes. The orientation of the barrel vaults unambiguously determines the orientation of the holes. The holes therefore make the same angles as the barrel vaults, relative to the axes of the chamber.

The surgeon then threads the screws 9 into the barrel vaults 7. The barrel vaults direct the screws along the correct path. Due to the interaction of the heads of screws 9 with the barrel vaults, the barrel vaults also insure that the screws 9 become inserted to the correct depth. When tightened, the screws 9 tend to draw the adjacent vertebrae towards the chamber. Note also that the screws pass twice through the cortex of the vertebrae. In other words, each screw has a length sufficient to pass through the cortex 27 at one surface of the vertebra, then through the cancellous material 29 at the core of the vertebra, and again through the cortex as the screw exits the vertebra. Fastening the screws in this manner minimizes the likelihood that the screws will become dislodged.

Following the tightening of the screws, one can take a lateral X-ray to verify proper placement of the screws. If all is correct, one can then close the wound in the conventional manner.

The present invention has many advantages, as outlined below:

1. The fusion stabilization chamber does not rely on screws as the sole means of stabilizing the spine following surgery. Due to the trape-

zoidal cross-section of the chamber, the chamber becomes firmly wedged within the corpectomy site even before attachment of the screws.

2. The surgeon can learn to insert the fusion stabilization chamber much more quickly than devices of the prior art. Since the barrel vaults automatically determine the direction and depth of the screws, the surgeon will be less likely to make mistakes while using the present invention, and the invention therefore is less intimidating to the surgeon than devices of the prior art. In particular, the oblique direction of the screws lessens the potential damage to the spinal cord. Moreover, most neurosurgeons can use the fusion stabilization chamber with instruments already in their possession.

3. The oblique direction of the screws has the added benefit that it increases the compression effect, by drawing vertebrae above and below the chamber into firm contact with the chamber. Such compression speeds fusion of the bone.

4. The oblique direction of the screws has the additional advantage of reducing the required size of the surgical incision, because the surgeon can reach deeply into adjacent vertebrae, using the screws, without exposing those vertebrae.

5. Because of the ease and manner of insertion of the device, the surgeon need not use intraoperative fluoroscopy, or other monitoring means, while inserting the device.

6. The present invention eliminates the need for a large inventory of stabilization plates and screws for fitting different sizes of vertebrae. One can construct the present invention in two or three basic sizes, which together fit virtually all possible corpectomy sites, due to the telescoping feature of the chamber. Thus, the invention reduces the cost of maintaining an inventory of materials. Moreover, due to the

simple structure of the fusion stabilization chamber, one can manufacture it relatively inexpensively.

7. One can make the fusion stabilization chamber of strong titanium metal mesh which allows bone to grow from end to end and from side to side. One can easily fill the chamber with the patient's own cancellous bone mixed with hydroxyapatite crystals and/or other biocompatible synthetic bone substitutes known to increase the rate of bone formation. Thus, the present invention reduces the need to harvest bone from other sites on the patient's body.

8. The structure of the fusion stabilization chamber provides stability through all three degrees of freedom of movement.

In an alternative embodiment, one can replace the locking screw with a screw device located inside the chamber and extending along the entire length of the chamber. Thus, the latter screw device would comprise a type of jack. Turning the latter screw would vary the overall length of the jack, which is equivalent to varying the length of the chamber. With this arrangement, one need not adjust the length of the chamber before inserting it into the corpectomy site. Instead, one would first insert the chamber, and then turn the screw to adjust the jack, until the chamber becomes long enough to occupy the entire space. The above-described screw device would then comprise the means for locking the hollow members into a fixed position relative to each other, and could be used instead of, or in addition to, locking screw 11. One would use a bevel gear, or equivalent mechanical device, for adjusting the jack while the chamber is in position. The latter alternative should be considered within the scope of the present invention.

In another alternative embodiment, one can coat the outside of the

chamber with an osteoconductive substance, such as hydroxyapatite, or the like, to promote fusion of the chamber to the surrounding bone. This coating can be instead of, or in addition to, the filling of the chamber with bone material. The invention should be considered to include the latter alternatives.

The chamber used in the present invention can have various cross-sections. The invention is not limited to the rectangular or trapezoidal cross-sections discussed above, but can include other shapes. For example, one could form the chamber with a circular cross-section, in which case the chamber would have the general shape of a cylinder.

The present invention is also not limited to a chamber having straight walls. Instead, the chamber could be curved along its length. In this way, one can make the chamber fit the curvature of the spine. In the latter case, both hollow members would be curved, so that they could slide back and forth within each other, while maintaining the desired curvature. This embodiment would be useful for a corpectomy which spans a relatively large number of vertebrae.

While the above description illustrates the preferred embodiments of the invention, one can vary the invention in still other ways. For example, as noted above, one can vary the structure of the walls of the chamber. While one prefers a chamber having holes, such as provided by a metal mesh, one could use an empty box having solid walls. The position and number of barrel vaults can also vary. These and other modifications, which those skilled in the art will recognize, should be considered within the spirit and scope of the following claims.

What is claimed is:

1. A fusion stabilization chamber, comprising:
 - a) first and second hollow members, the first hollow member being slidable within the second hollow member,
 - b) both hollow members including at least one barrel vault for receiving a screw therein, at least one barrel vault of the first hollow member being mutually oblique to at least one barrel vault of the second hollow member,
 - c) wherein at least a portion of each hollow member includes a wall having openings.
2. The fusion stabilization chamber of Claim 1, wherein the hollow members have walls formed of a metal mesh, wherein said openings are defined by the mesh.
3. The fusion stabilization chamber of Claim 1, wherein each barrel vault includes a screw threaded therein.
4. The fusion stabilization chamber of Claim 1, further comprising means for locking the two hollow members in a position such that the hollow members together define a predetermined volume.
5. The fusion stabilization chamber of Claim 1, wherein each hollow member is attached to a stabilizing plate, the stabilizing plates lying in generally the same plane, each stabilizing plate extending longitudinally outward from the hollow member.
6. The fusion stabilization chamber of Claim 5, wherein at least one stabilizing plate has a threaded hole, and a screw inserted through said threaded hole.
7. The fusion stabilization chamber of Claim 6, wherein each barrel vault includes a screw threaded therein.

8. The fusion stabilization chamber of Claim 1, wherein the hollow members have a slightly trapezoidal cross-section.

9. A fusion stabilization chamber, comprising:

a) first and second hollow members, the first hollow member being slidable within the second hollow member, the hollow members having a slightly trapezoidal cross-section,

b) both hollow members including at least two threaded barrel vaults with screws threaded in the barrel vaults, the barrel vaults of the first hollow being oblique to the barrel vaults of the second hollow member,

c) the hollow members being formed generally of a metal mesh, and

d) means for locking the two hollow members in a position such that the hollow members together define a predetermined volume.

10. The fusion stabilization chamber of Claim 9, wherein each hollow member is attached to a stabilizing plate, the stabilizing plates lying in generally the same plane, each stabilizing plate extending longitudinally outward from the hollow member.

11. The fusion stabilization chamber of Claim 10, wherein the stabilizing plates have threaded holes, and wherein there are screws inserted through said threaded holes.

12. A fusion stabilization chamber, comprising:

a) first and second members, the first member being movable with respect to the second member, and means for fixing the first and second members in a desired position relative to each other, and

b) means, attached to the first and second members, for affixing said first and second members to vertebrae adjacent a corpectomy site.

13. A method of stabilizing the spine following spinal surgery in which at least a portion of one or more vertebrae of the spine is removed, the area from which the vertebrae are removed being called the corpectomy site, the method comprising the steps of:

- a) measuring the length of the corpectomy site,
- b) adjusting the length of a telescoping chamber such that the chamber has a length substantially equal to the length of the corpectomy site,
- c) filling the chamber with bone material,
- d) inserting the chamber into the corpectomy site, and
- e) screwing a plurality of screws through threaded barrel vaults mounted to the chamber, the screws being screwed into vertebrae adjacent to the corpectomy site.

14. The method of Claim 13, wherein the adjusting step includes the step of tightening a locking screw to fix the length of the chamber at a desired value.

15. The method of Claim 13, wherein the filling step is done with bone material which has been removed from the corpectomy site.

16. The method of Claim 13, wherein the screwing step is preceded by the step of drilling holes into said adjacent vertebrae, the screws being screwed into said holes.

17. The method of Claim 13, wherein the screws are inserted to a depth sufficient to extend completely through at least one vertebra.

18. A method of stabilizing the spine following spinal surgery in which at least a portion of one or more vertebrae of the spine is removed, the area from which the vertebrae are removed being called the corpectomy site, the method comprising the steps of:

- a) measuring the length of the corpectomy site,
- b) adjusting the length of a telescoping chamber such that the chamber has a length substantially equal to the length of the corpectomy site, and
- c) inserting the chamber into the corpectomy site, and affixing the chamber to vertebrae adjacent to the corpectomy site.

1/3

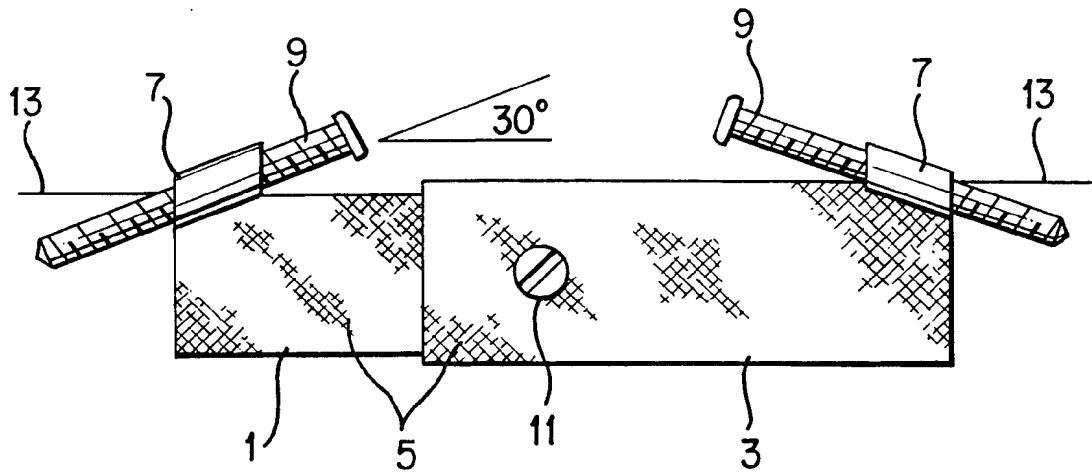


FIG. 1

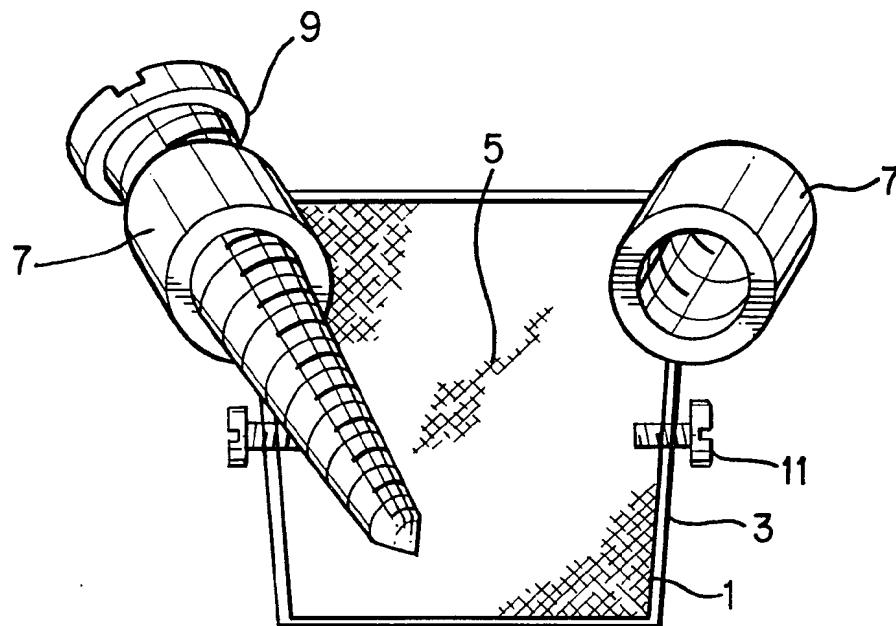


FIG. 2

2 / 3

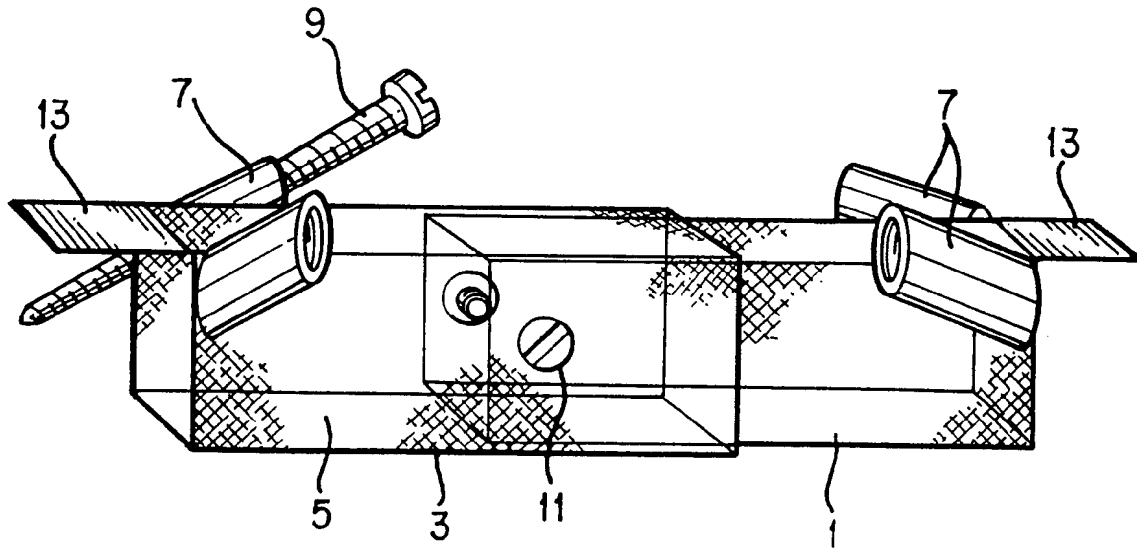


FIG. 3

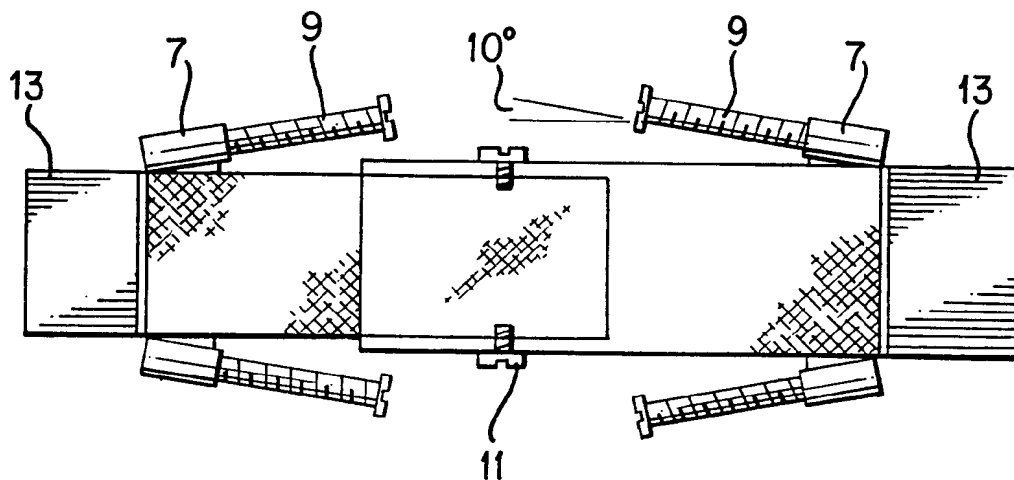


FIG. 4

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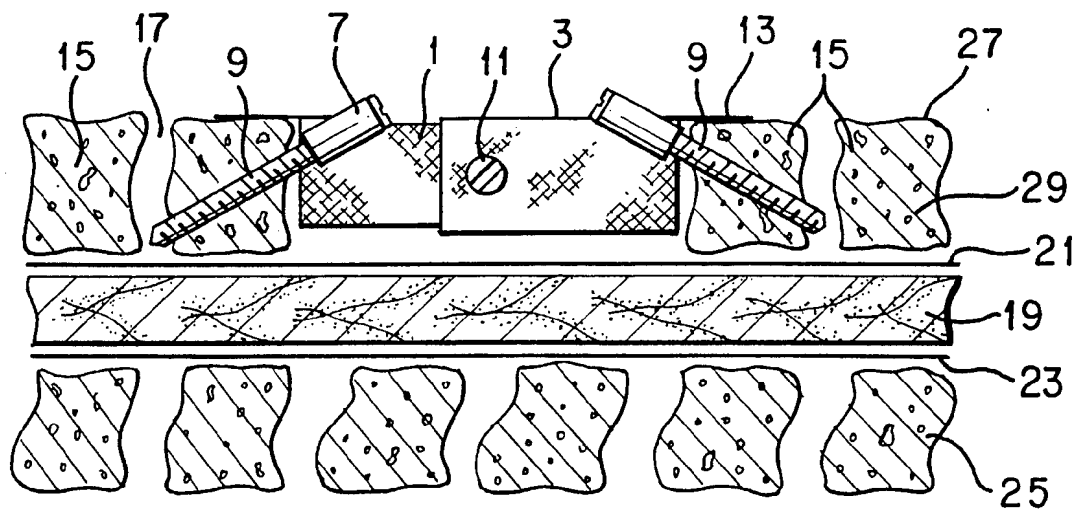


FIG. 5

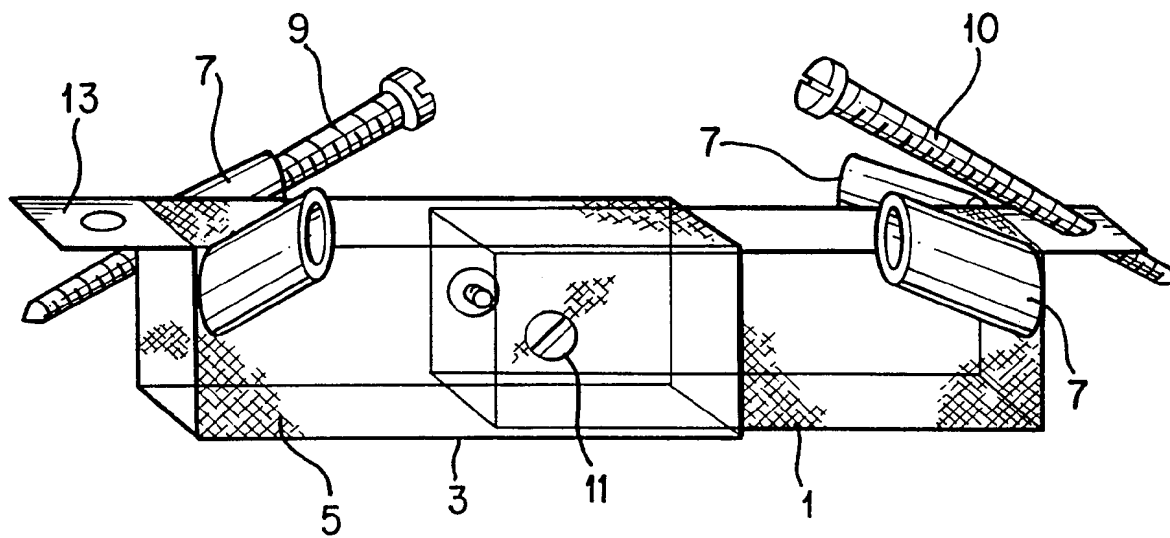


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/01484

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 2/44

US CL :606/61; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 403/109; 606/61; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P ----- Y, P	US, A, 5,236,460, (BARBER), 17 August 1993. Note feature (48) in Fig. 4, and column 1 lines 31-33.	12, 18 ----- 1, 3-5
Y	US, A, 5,002,576, (FUHRMANN ET AL.), 26 March 1991. See column 3, lines 44-49.	1, 3-5
X --- Y	JP, A, 4114644, (YASUI), 05 April 1992. See the figures.	1, 3-8, 12-16, 18 ----- 2, 9-11, 17
E, Y	US, A, 5,290,312, (KOJIMOTO ET AL.), 01 March 1994. See the entire document.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB94/01455 (22) International Filing Date: 5 July 1994 (05.07.94) (30) Priority Data: <table border="0"><tr><td>9314057.2</td><td>7 July 1993 (07.07.93)</td><td>GB</td></tr><tr><td>9314471.5</td><td>7 July 1993 (07.07.93)</td><td>GB</td></tr><tr><td>9314056.4</td><td>7 July 1993 (07.07.93)</td><td>GB</td></tr><tr><td>9314580.3</td><td>14 July 1993 (14.07.93)</td><td>GB</td></tr><tr><td>9320352.9</td><td>2 October 1993 (02.10.93)</td><td>GB</td></tr><tr><td>9320368.5</td><td>2 October 1993 (02.10.93)</td><td>GB</td></tr></table> (71) Applicant (for all designated States except US): SMITH & NEPHEW PLC [GB/GB]; 2 Temple Place, Victoria Embankment, London WC2R 3BP (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): WOLOWACZ, Sorrel, Elizabeth [GB/GB]; 99 Carr Lane, Acomb, York YO2 5NH (GB). CARTER, Andrew, James [GB/GB]; 80 Debden Road, Saffron Walden, Essex CB11 4 AL (GB). SEARLE, Richard, John [GB/GB]; 12 Fairway Drive, Upper Poppleton, York YO2 6HE (GB). MATTHEWS, Jane, Bridget [GB/GB]; 84 South Bank Avenue, York YO2 1DP (GB). KING, John, B. [GB/GB]; Well Cottage, Chiselhurst Road,			9314057.2	7 July 1993 (07.07.93)	GB	9314471.5	7 July 1993 (07.07.93)	GB	9314056.4	7 July 1993 (07.07.93)	GB	9314580.3	14 July 1993 (14.07.93)	GB	9320352.9	2 October 1993 (02.10.93)	GB	9320368.5	2 October 1993 (02.10.93)	GB	Bromley, Kent BR1 2NW (GB). PALMER, Debra [GB/GB]; Shaftesbury, Ten Acres, Dorset SP7 8PW (GB). (74) Agent: WHITE, Martin; Corporate Patents & Trade Marks Dept., Smith & Nephew Group Research Centre, York Science Park, Heslington, York YO1 5DF (GB). (81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
9314057.2	7 July 1993 (07.07.93)	GB																			
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9320352.9	2 October 1993 (02.10.93)	GB																			
9320368.5	2 October 1993 (02.10.93)	GB																			
(54) Title: IMPLANTABLE PROSTHESIS, KIT AND DEVICE FOR MANUFACTURING THE SAME																					
(57) Abstract An implantable prosthesis comprises a biocompatible, synthetic, substantially bioresorbable matrix material seeded with fibroblasts.																					

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IMPLANTABLE PROSTHESES, KIT AND DEVICE FOR MANUFACTURING THE SAME

The present invention relates to methods suitable for replacing or repairing broken or damaged connective tissue such as ligaments or tendons and to prostheses for use in such methods. Also disclosed is a device for use in forming such prostheses, as well as kits from which the prostheses can be formed.

It is known from United States Patent No. US5078744 to repair damaged ligaments such as the anterior cruciate ligament (ACL) by replacing part of the damaged ligament by a prosthetic ligament comprising purified connective animal tendon or ligament tissue fibres which are cross-linked and formed into groups of aligned fibres.

The most common method of repair or reconstruction of the ACL is to implant a prosthetic graft comprising autogenous tissues. Thus it is common surgical practice to harvest autogenous tissue eg. patellar tendon from the host and to form a prosthesis for implantation.

A number of synthetic non-bioresorbable materials have been used in the manufacture of prosthetic ligaments, the materials being chosen for their affinity for supporting or encouraging the ingrowth of fibroblasts, after implantation of the prosthesis.

According to the present invention there is provided an implantable prosthesis which, in a form prior to implantation in a host, comprises a biocompatible, synthetic, substantially bioresorbable matrix material seeded with fibroblasts.

By "synthetic", is merely meant a material which is not used naturally by the mammalian body in connective tissue repair or which is not a chemically modified form of such a material. Thus this term excludes collagen and artificially cross-linked collagen matrixes (although, if desired, collagen can be used in addition to the synthetic material).

The term "fibroblast" includes cells which are sometimes referred to as fibroblast, fibrocyte, tenocyte or synovioctye cells. This term also covers precursor cells to any of these cells.

5 By "substantially bioresorbable matrix material" is meant a three dimensional structure for supporting fibroblasts (which may be in the form of a scaffold, mesh or solid structure, for example) and which, in the implanted prosthesis, degrades substantially over time in a mammalian body, due to the chemical/biological action of body
10 components (as opposed to simply breaking due to physical strain on to the prosthesis). Desirably after the prosthesis has been implanted in an adult human for five years (more preferably after only one year's implantation) the bioresorbable material will have degraded to such an extent so that it makes no substantial
15 contribution to the structural integrity of the prosthesis.

Preferably the matrix may additionally comprise one or more of the following molecules: proteoglycans, glycosaminoglycans, fibronectin or its active binding domain, or one or more growth
20 factors e.g. bone morphogenetic protein (BMP) fibroblast growth factor, angiogenesis factor or other stimulatory factors.

In a further embodiment of the invention, the prosthesis or part thereof (e.g. area(s) of the prosthesis which will come into contact
25 with bone after implantation), may be impregnated with osteoinductive or osteoconductive agents, to enable more easy infiltration by bone cells. Examples of suitable osteoinductive materials susceptible to infiltration include hydroxyapatite, freeze-dried or demineralised bone, growth factors (e.g. bone
30 morphogenetic protein) etc. Impregnation may suitably be just before implantation of the prosthesis. Aptly such materials are incorporated into ends of the prosthesis.

In a further embodiment of the present invention, there is
35 provided a method of repairing or replacing damaged connective tissue in a human or non-human animal comprising the steps of: incubating a biocompatible, synthetic, substantially bioresorbable

matrix material in the presence of a suitable culture medium and of fibroblasts under suitable conditions for fibroblast seeding on or in the matrix and thereafter implanting the seeded matrix into a host.

5 Examples of suitable substantially bioresorbable synthetic polymers include polylactide (PLA), polyglycolide (PGA), polydioxanone, poly caprolactone (PCL), polyhydroxybutyrate (ICI BIOPOL™), polyhydroxybutyrate-co-hydroxyvalerate (ICI BIOPOL™), polyanhydrides, polyorthoesters, polyorthocarbonates, 10 polyaminocarbonates, polytrimethylene carbonate and co-polymers incorporating monomers from which the aforesaid polymers can be formed.

 When the prosthesis according to the present invention 15 comprises a copolymer, the copolymer may incorporate hydroxyvalerate and hydroxybutyrate monomers. In such copolymers the amount of hydroxyvalerate present may be from 1 to 47% mol. Other particularly suitable copolymers are PLA/PGA and PLA/PCL copolymers.

20 Composites of a plurality the above substantially bioresorbable materials may also be suitable as or as part of the matrix material.

 The matrix be fabricated of two or more distinct materials (e.g. 25 distinct fibre types) with different degradation rates, providing a two or more phase loss of mechanical properties with time. Also, the different fibre types may possess different mechanical properties. For example, highly extendable fibres may be combined with less extendable fibres. The matrix may be designed to elongate to a 30 specified extent before the less extendable fibres prevent further extension. This design may be advantageous in exposing the cells to limited and controlled strain while protecting against damage to the forming tissue. For example, polycaprolactone fibres have a lower Young's modulus than polylactide fibres.

35 Furthermore, one polymer may be coated with another polymer. This is advantageous where the material of choice on the

basis of mechanical properties is not necessarily the material of choice for cell culture (unless it is modified). Here a more biocompatible polymer may be used to coat a less biocompatible base material. For example, polylactide provides a better substrate
5 for fibroblast proliferation than polycaprolactone. Polycaprolactone fibres could be coated with polylactide to improve compatibility with fibroblasts.

As indicated above, copolymeric materials may be used. This
10 can be advantageous where the copolymers possess degradation rates intermediate between the rates of the homopolymers of which they are composed. Therefore, the degradation rate may be controlled by controlling the composition of the copolymer. Also, production of copolymer fibres by fibre spinning or extrusion may
15 yield fibres with mechanical properties superior to those of homopolymers. Polylactide-Polyglycolide copolymers are good examples of both of these points.

Suitable fibroblasts for use in seeding the matrix may be
20 autogenic fibroblasts, allogenic fibroblasts or xenogenic fibroblasts. Preferably, the fibroblasts are autogenic. The fibroblasts may originate from for example the dermis, tendons or ligaments. The fibroblasts for use in seeding the matrix may comprise a mixture of one or more of the above types of fibroblasts. Where the fibroblasts
25 are autogenic, it is preferable to isolate them from the dermis, as this avoids the need for extensive invasive surgery.

The fibroblasts may be obtained according to any suitable method. A preferred method is by carrying out a skin biopsy.
30

The matrix material may be seeded with fibroblasts by placing the matrix in a culture vessel containing an appropriate culture medium (e.g. DMEM), in the presence of fibroblasts and incubating under cell culture conditions. The fibroblasts may be suspended in
35 the culture medium and the resultant suspension added to the culture vessel either before or after addition of the matrix. The

number of fibroblasts/ml of medium may be varied according to the degree of seeding it is desired to establish.

5 The prosthesis of the present invention may be used to either
partially or totally replace a damaged ligament, tendon, cornea,
dermis, dura (or other body part comprising connective tissue).
Where the damage is substantial, the damaged ligament or tendon
may be totally surgically replaced by the prosthesis. Where the
damage is less substantial the matrix may be designed so as to be
10 joined (e.g. by suturing) to the existing damaged ligament or tendon.

 The matrix may be designed according to any one of a number
of possibilities. Aptly the matrix is a fibrous structure. It may have
loops or other structures at each end for aiding fixation to bone
15 (using for example either the "two tunnel" or the "over-the-top"
technique). It may be formed by any appropriate technique - e.g.
braiding, knitting, weaving, crocheting etc. The matrix is desirably in
elongate form and is preferably flexible.

20 The device may closely mimic the natural structure and fixation
of the ligament or tendon. For example, for ACL reconstruction, the
device could be composed of a hierarchy of fibres bundled together
in fascicular units, passing directly from the femur to the tibia or
taking a spiral path around the axis of the device. Fixation may be to
25 the natural fixation areas of the ligament or tendon. Any appropriate
fixation means may be used (e.g. screws, nails, staples or sutines).
The fixation means may itself be bioresorbable, for example it may
be formed of polyhydroxybutyrate.

30 The present invention further provides a kit for forming the
prosthesis of the present invention comprising a synthetic
biocompatible matrix material and a source of fibroblasts.

 On incubation under suitable conditions, the fibroblasts will
35 grow on and/or in the matrix, thus producing a matrix seeded with
fibroblasts.

The kit may additionally comprise a suitable medium for the proliferation of fibroblasts.

5 Ideally the kit is presented in a sterile package. Alternatively the parts of the kit may be sterilised just before use. Prior to implantation, the components of the kit can be incubated together under appropriate culture conditions as above described to allow the fibroblasts to seed the prosthesis.

10 The fibroblasts may be in any suitable form ready for use. Thus aptly the fibroblasts may be cryopreserved.

15 The matrix, or components/precursors thereof, may be provided in lyophilised form.

20 In a preferred embodiment, the present invention comprises, an implantable prosthesis which in a form prior to implantation comprises a biocompatible synthetic substantially bioresorbable matrix material having a polymeric gel in intimate contact therewith, the gel having fibroblasts dispersed therein. This is advantageous in that the gel can support the cells in a true three-dimensional arrangement rather than merely supporting a monolayer on the surface of a material. The environment closely mimics the natural physiological environment of the cells. Also, incorporation of cells in a gel can provide for even cell distribution, preventing cells from pooling which might otherwise occur due to gravitational influence.

30 The present invention provides a method of repairing or replacing connective tissue in a human or other animal, comprising the steps of: incubating a biocompatible matrix material in the presence of a gel-forming composition and of fibroblasts under suitable conditions to form a prosthesis comprising a matrix contacting a polymeric gel, the gel having fibroblasts dispersed therein, and thereafter implanting the prosthesis into a host.

35 Suitable gel forming compositions include collagen gel forming compositions and fibrin gel forming compositions.

Fibroblasts in a collagen gel are capable of utilising the collagen and reorganising it. Under an appropriate mechanical stimulus they are capable of reorganising the fibrils into non-
5 randomly orientated, organised structures resembling the natural ultrastructure of ligament and tendons. A mechanical stimulus may be the prevention of gel contraction which would otherwise occur over time by fixing the gel at two points. The matrix may be designed to achieve this. Alternatively, the gel on or in the matrix
10 may be exposed to applied strain using a mechanised straining device to stimulate fibroblast alignment.

The method may comprise an additional step of incubating a gel-contacting matrix under suitable conditions for fibroblast
15 proliferation in the gel and thereafter implanting the matrix into a host.

In the preferred embodiment of the present invention, the matrix is seeded by means of incubating the matrix in the presence
20 of a suitable culture medium, a gel-forming composition and the fibroblasts to be seeded. An appropriate agent for causing gelation of the gel forming composition may also be used, if necessary.

Seeding the matrix in the presence of a gel-forming
25 composition, fibroblasts (and a gelling agent, if required) results in a gel-coated or filled matrix, the gel having fibroblasts dispersed therein. The gel can be formed by the interaction of the gelling agent and the gel-forming composition. A preferred gel is a collagen gel. A Type I, II or III collagen solution may be prepared using an
30 appropriate source of collagen. Thus for example a Type I collagen solution may be prepared from dermis (Type I collagen forms up to 70% of extracellular protein found in skin) as above described. Alternatively a Type I collagen solution may be prepared tendons, e.g. rat or bovine tendons, which comprise almost exclusively Type
35 1 collagen. The collagen may be extracted according to any of the standard methods known by those skilled in the art.

There are a number of suitable ways of incorporating the gel in or on the matrix. For example, the matrix may be suspended in such a manner that the gel-forming solution (optionally comprising fibroblasts) completely surrounds the matrix. A mould which
5 surrounds the matrix may be used. Centrifugation or suction may alternatively be used to direct gel towards the matrix.

A kit for use in forming the prosthesis of the preferred embodiment can comprise a biocompatible matrix, a gel-forming
10 composition and a source of fibroblasts.

Alternatively the kit may comprise a biocompatible matrix having a coating comprising a polymeric gel and/or having a polymeric gel incorporated therein and a source of fibroblasts. On
15 incubation under suitable conditions the fibroblasts can invade the gel, thus producing a matrix bearing a gel having fibroblasts therein.

The prosthesis of the present invention offers an advantage over previously known prostheses which were designed to enhance
20 ingrowth of fibroblasts after implantation and act as a scaffold through which fibroblasts can grow and form a new ligament, since it comprises fibroblasts prior to implantation. Thus the damaged tissue may be replaced by a prosthesis comprising viable fibroblasts which may be replicating. The fibroblasts may already substantially be
25 aligned on implantation or at least oriented in a non-random manner. This process is speedier than previously known methods which rely on infiltration of prostheses by fibroblasts after implantation. It will be clear that the prosthesis may be implanted after an initial predetermined incubation period timed to result in
30 seeding of the prosthesis with fibroblasts. Alternatively the prosthesis may be incubated for a longer incubation period than the initial incubation period so that the fibroblasts will be replicating and will have already started to secrete collagen fibrils when the prosthesis is implanted.

35

The prosthesis and method of the present invention offers other advantages over the common surgical practice or harvesting

host patellar tendon in that it avoids the need for carrying out an extensive surgical operation to harvest the tendon. A simple skin biopsy (a standard procedure which does not result in substantial scarring) can be used to obtain fibroblasts which can then be
5 proliferated in culture. In addition, the prosthesis can be designed to optimise fibroblast orientation. The cumulative effect of these advantages can result in a reduction in the length of a hospital stay.

10 In one preferred embodiment of the present invention, where a collagen gel contacts the matrix, the prosthesis of the present invention provides a source of collagen which can be used by the fibroblasts. The collagen in the gel is preferably in a non-cross-linked form.

15 In another preferred embodiment of the present invention a fibrin gel is used.

According to a further aspect of the present invention there is provided a device for culturing cells for use in forming a prosthesis
20 according to the present invention, comprising a chamber for maintaining fibroblasts in a viable condition, the chamber being provided with means for releasably securing the matrix material and means adapted for applying strain to the matrix material along a single axis only. Such a device can be included in a kit as aforesaid.

25 If several straining means are present, the device of the present invention can apply strain to a plurality of samples at any one time. Thus the device may have one or more chambers adapted to retain a culture medium and may be provided with means for
30 releasably securing a plurality of matrix materials. This may be done simultaneously. Each of several chambers may be provided with means for releasably securing a plurality of matrix materials. Alternatively each chamber may be provided with means for
35 releasably securing a single matrix material.

A chamber may be permanently fixed within the device. Alternatively the chamber may be releasably fixed so that it may be

removed from the device as desired, e.g. the chamber(s) may be removed to facilitate the securing and release of the matrix material.

5 A chamber may be made from any material which may be sterilised by suitable methods of sterilisation, e.g. gamma irradiation, steam sterilisation or ethylene oxide (ETO) sterilisation.

10 A chamber may have any desirable shape and size. Suitably the chamber may be cylindrical, cuboid or spherical. The dimensions of the chamber should be such that they enable the matrix material to be secured and to be subsequently extended on the application of strain. The device of the present invention can be adapted to apply a strain which causes e.g. up to 100% extension of the matrix material (relative to the material in unextended form).
15 Generally speaking however, an extension of up to 10%, or of up to 5% may be sufficient.

20 Thus the dimensions of the chamber can be such that they enable the matrix material to be extended to the desired level.

The dimensions of a chamber are desirably such that the chamber has a capacity of up to 75cm^3 , e.g. up to 50cm^3 . The chamber may be made from any suitable material, e.g. stainless steel or Perspex™ material. Preferably the material is autoclavable
25 to facilitate sterilisation.

30 Preferably the chamber is provided with a transparent or translucent window to enable the matrix material to be viewed during the time of culture. Examples of suitable materials include glass and polymethylmethacrylate (PERSPEX).

35 The chamber may comprise a closure, which may be removably or hingedly mounted to allow access to the inside of the chamber. Thus for example the chamber may comprise a glass cylinder wherein at least one of the ends is removable. Aptly the chamber may be collapsible or telescopic.

The chamber is desirably thermostatically controlled and may be heated via a water jacket or other heating means. It may be provided with various sensors e.g. sensors of the CO₂ content within a head space of the chamber. A CO₂ source may also be provided.

The matrix material may be releasably secured by securing means within the chamber.

10 The means for applying strain may compare two elements which are movable within the chamber so that the spacing between the elements can be varied. Alternatively one element may be movable but the other may be fixed.

15 The securing means may be any suitable means for releasably securing the matrix sample. The design of the securing means depends upon the design of the ends of the matrix material. Thus for example where the matrix material comprises looped ends the securing means may comprise a pair of clips or hooks. Suitably the
20 securing means may comprise for example a chuck or a lathe or jaws which may screw together or be held by springs. Aptly the securing means may be in the form of a slot or other opening such that the ends of the matrix material are designed to fit thereon. Thus for example the ends of the matrix material may be embedded in a
25 resin which may be retained in a slot. The opposite arrangement can be used in which the opening is in the matrix material and the securing means fit therein. A yet further way of releasably securing the matrix material is to provide a spool, which may be generally cylindrical, about which matrix material can be wrapped and held in
30 position by friction. The spool may be held in place by a gripping device. Two such spools may be provided - one for each of two gripping devices.

35 The matrix material to which strain is to be applied by the device of the present invention may comprise any suitable material for supporting viable cells. Cells may be present in or along the entire length of the matrix material. Alternatively part of the matrix

material, e.g. the ends thereof, may have no cells. The cells may be applied to the matrix material either before or after the matrix material has been secured under extension. It is preferable however to apply the cells to the material before securing the material under extension in the chamber.

The matrix material may be designed in the form of a prosthetic ligament or tendon. Where for example the matrix material is in the form of a prosthetic ligament, the ligament when unstrained is preferably in the range of from 1 to 30cm long. The matrix material should be chosen so that it is suitable for withstanding the magnitudes of strain which it will be subjected to on implantation, e.g. in the knee.

The means for applying strain may act by pulling both ends or one end of the matrix material, resulting in an extension of the matrix material. This may be done by various means, e.g. mechanical, electrochemical, electrical, piezoelectric, pneumatic, hydraulic or other means. The matrix material may be releasably attached to a stationary element at one end of the chamber and the opposing end of the matrix material may be attached to a tension applying member (for example a winding device). Suitably strain may be applied to the matrix material by means of a diaphragm, one side of the diaphragm lying within the chamber and the opposing side lying outside the chamber. A pivotally mounted lever may be used to apply strain.

The present invention also provides a method of culturing cells under strain which method comprises the steps of releasably securing a matrix material having viable cells in intimate contact therewith in a chamber, the chamber comprising an adequate amount of culture medium to cover the matrix and cells, and applying strain to the matrix material along a single axis.

Materials suitable for use in a matrix of the present invention can be assessed as exemplified below:-

Assessment of Materials

5

In order to make an initial assessment of suitable materials for supporting fibroblast growth, various materials were obtained (which are not to be construed as limiting), as indicated in Table 1 below, and moulded into films for 5min at 2.5 Tons at the following
 10 temperatures: Polylactide 170°C; polyglycolide, 245°C; polyhydroxybutyrate, 185°C; and polycaprolactone, 65°C.

Table 1

15	<u>Material</u>	<u>Supplier</u>	<u>Fig.</u>
	Polylactide	Medisorb, Cincinnati, Ohio, USA	1a
	Polyglycolide	Medisorb, Cincinnati, Ohio, USA	1b
	Polyhydroxybutyrate	Goodfellows, Cambridge, UK	1c
20	Polycaprolactone	Birmingham Polymers Inc. Alabama, USA	1d

Fibroblasts were seeded onto the surfaces of these materials at a density of 1×10^4 cells/cm² of material and incubated for 3
 25 days under culture conditions.

After the incubation period, photomicrographs were taken of the cell-seeded samples. These are shown in Figs. 1a to 1d for the samples indicated in Table 1 above (photocopies of all of the
 30 photographs provided for this application are provided immediately after the relevant photographs).

Fibroblasts can be seen to be well adhered to the surfaces of all of the materials and to exhibit the morphology typical of healthy
 35 cultural fibroblasts.

One sample of fibroblasts was grown on polylactide as described above apart from the fact that a longer (16 day) culture period was used.

- 5 After this period the cells were stained with a viable stain (calcein AM (2 μ M)) and visualised by fluorescence microscopy using a fluorescein filter. A confluent monolayer of viable cells was observed, showing that polylactide is capable of supporting viable fibroblasts for extended periods of culture.
- 10
- Figure 2 is a graph showing the relative rate of proliferation of fibroblasts on four examples of bioresorbable synthetic materials: polylactide (PLA); polyglycolide (PGA) polyhydroxybutyrate (PHB) and polycaprolactone (PCL) (all as described above) in comparison with a tissue culture treated polystyrene (TCP) control (since TCP is known to support good fibroblast growth).
- 15

- Figures 2a) to e) show each of these materials on a single graph (for each of reference). Cells were seeded at 1×10^4 cells.cm⁻² in triplicate and the rate of proliferation determined by measuring the uptake of tritiated thymidine into cellular DNA at timepoints up to 7 days after incubation using standard cell culture techniques. The medium was changed at 2, 4 and 6 days. The points represent the mean of three determinations and the error bars represent the range. All polymers supported fibroblast proliferation.
- 20
- 25

- Figure 3 is a photomicrograph of fibroblasts embedded within a three dimensional collagen gel after 15 days of culture. The cell-seeded gel was prepared as described in example 2 (which will be described later) apart from the fact that it was not used to contact a matrix. The gel provides a three-dimensional structure in which the cells are embedded and can form interactions with collagen molecules via membrane integrin receptors. The cells are randomly arranged, exhibit long processes and are capable of reorganising collagen fibrils within the gel.
- 30
- 35

Figure 4 is a photomicrograph of fibroblasts embedded within a three dimensional collagen gel as described for Fig. 3 above, apart from the fact that the gel has now been constrained from contracting in one direction by two stainless steel pegs glued to a culture dish with a tissue culture compatible adhesive. The cells are arranged in a highly orientated fashion, their long axes being parallel to the axis between the contraining pegs. The collagen fibrils align along the same axis. This effect is due to the pegs preventing the gel contracting, as would otherwise occur in the presence of fibroblasts in culture.

The following examples, which are not to be construed as limiting, illustrate how various cell-seeded matrixes can be produced.

5

Example 1 : Preparation of a fibroblast seeded polylactide matrix prosthesis

a) Preparation of Cells

10

A biopsy is washed three times in phosphate buffered saline (PBS), and rinsed in 70% alcohol. The rinsed biopsy is then dipped into Dulbecco's Modified Essential Medium (DMEM) and incubated at 37°C for 24 hours. After incubation, the biopsy is cut into small
15 pieces under PBS. The cut pieces are transferred to a 50mm petri dish, containing about 5ml of collagenase solution to allow digestion. The epidermal sheets are removed from the collagenase solution. The resultant solution is centrifuged. The fibroblast cell pellet is resuspended in DMEM and thereafter seeded in a 35mm
20 petri dish using DMEM. The cells may be confluent in from 2-4 days. Thereafter the cells may be cultured to provide an appropriate quantity of fibroblasts for seeding the matrix.

A suitable medium for culturing the isolated fibroblasts may
25 comprise DMEM which may be supplemented with the following: glutamine, foetal calf serum, non essential amino acids and antibiotics. In addition the medium may have a buffering agent such as bicarbonate.

30 b) Preparation of matrix material

A polylactide matrix material suitable for use in a prosthesis for replacing a ligament can be prepared by obtaining polylactide fibres and then braiding them to form a braid of appropriate dimensions to
35 replace the ligament.

Poly lactide fibres can be obtained by extrusion, fibre spinning, melt-spinning, drawing, heat annealing etc.

Braiding of the fibres can be done by standard braiding techniques, the length and thickness of the braid, number of fibres present and diameter of fibres present being selected to form a
5 braid with appropriate properties.

The ends of the device are constructed in a suitable way to aid fixation of the device by a screw or other fixation means. This is done by forming eyelets at the ends.

10

c) Seeding of matrix material with cells

The braided device is incubated in a medium containing 10% v/v serum for 24 hours and is then seeded with cells by pipetting a
15 cell suspension over the surface of the matrix material until the latter is completely covered with cell suspension. (Alternatively the matrix may be incubated together with the cell suspension for a period of about six hours under conditions of agitation, e.g. on a bottle roller. Other alternatives are to seed the device by sucking cell suspension
20 through it under vacuum (if it is porous) or by centrifuging cell suspension through the device).

d) Straining of the cell-seeded matrix

25 The cell seeded device is gripped at both ends in a straining apparatus which causes the device to be strained along a single longitudinal axis. This is done for sufficient time so as to cause the fibroblasts substantially to align along the general direction of the longitudinal axis, as can be assessed by microscopic analysis of the
30 cells. The apparatus comprises a culture chamber so that straining can occur over several hours or even several days and yet the cells can remain viable. Typically the device is strained at 37°C.

35 During straining a culture medium is used to culture the cells under suitable conditions. This includes serum, ascorbate or stable analogues thereof, together with growth factors.

The ascorbate stimulates the fibroblasts to synthesise collagen; the serum contains factors promoting cell proliferation and cell adherence and the growth factors can stimulate cell proliferation, development and migration.

5

e) Implantation of the cell-seeded matrix

Once the cell-seeded device has been strained for a sufficient period to obtain a desired degree of alignment of fibroblasts, it is removed from the cell-straining device and implanted into a patient by any desired technique.

10

Minimal invasive surgery is preferred. For a prosthetic anterior cruciate ligament implantation be done utilising the "two-tunnel" or the "over the top" techniques. Fixation can be achieved by using screws (or other fixation elements) placed through the eyelets of the matrix. The screws are suitably formed of a biodegradable material, such as polyhydroxybutyrate.

15

Example 2 : Preparation of a fibroblast seeded polylactide matrix prosthesis comprising a collagen gel in which the fibroblasts are incorporated

5

This can be done in an analogous manner to the method described in Example 1, except for the inclusion of an alternative procedure whereby fibroblasts are incorporated in a collagen gel which is used to seed the polylactide matrix. This extra procedure is described below:-

10

a) Preparation of collagen

It is desired to form the collagen in a form which is acid soluble and which is not cross-linked. This can be done as follows:-

15

Type I collagen is prepared from tendon but could be from other tissue e.g. skin. The tissue is minced finely, disinfected in 70% (v/v) ethanol for at least 30 mins, dispersed in acetic acid (1% v/v) and incubated with agitation at 4°C. The supernatant is removed and neutralised by addition of an appropriate volume of 1.0M sodium hydroxide. The precipitated type I collagen is pelleted by centrifugation at 8,000 x g and the pellet resuspended in an appropriate volume of acetic acid (1% v/v). The collagen concentration of this solution is determined by any appropriate method (e.g. a total protein assay - the BCA assay) and the concentration of the collagen solution adjusted appropriately (e.g. 3mg.ml⁻¹ can be used).

20

25

If the product is a kit, sterile collagen solution may be lyophilised and stored under vacuum or an inert gas (e.g. argon) to prevent cross-linking. A diluent (acetic acid) could also be provided. Alternatively, it could be provided as a solution and stored at 4°C to -20°C.

30

b) Seeding of matrix material with cells

Three components are typically used to seed the matrix:- cells
5 suspended in an appropriate medium, collagen solution and a
gelling agent - (e.g. 1M sodium hydroxide). The final collagen
concentration may be approximately 1mg.ml^{-1} and the seeding
density approx. 3×10^4 cells per ml of gel (or volume within the
matrix). The three components are maintained at 0°C to 4°C , mixed
10 and added to the matrix. Once the matrix is fully impregnated, it is
incubated at 37°C and gelling is initiated.

The impregnation of the matrix may be achieved by any
suitable method. The matrix may be merely immersed in the solution
15 within a mould. Alternatively the solution may be sucked into the
scaffold by use of a vacuum or forced in by centrifugation (for
example within a mould centrifuged at 500rpm for 5min at $0-4^\circ\text{C}$).

The rate of setting of the gel may be varied by varying the
20 temperature.

Example 3 : Preparation of a fibroblast seeded polylactide matrix prosthesis comprising a fibrin gel in which the fibroblasts are incorporated

5

This can be done by an analogous method to that described in Example 2, except that a fibrin gel rather than a collagen gel is used.

10

Again, three components are used: cell suspension, fibrinogen solution and thrombin solution containing calcium chloride (mM). The final cell concentration may be 3×10^4 cells per ml, the fibrinogen concentration may be 3mg/ml, the thrombin activity 2.5 Units/ml and the calcium chloride concentration 5mM. The reagents

15

are mixed and then incubated with the matrix. Once impregnated with the solution, the matrix is incubated at 37°C to allow rapid gelling. Impregnation of the matrix may be conducted by any of the techniques described above.

20

The rate of gelling may be varied by varying the thrombin activity and/or the temperature.

The cell straining device referred to previously will now be described by way of example only with reference to Figs. 5 a), b), c), d), and e) which show various components which can be put
5 together to form the device.

The device comprises a Perspex™ container 10 (shown in cut-away section) and lid 20 (see Figs. 5a) and 5e)). Container 10 can be used to contain an extensible material seeded with fibroblasts
10 under cell culture conditions. For ease of reference thermostats, sensors, inlets for topping up culture media and other components which would be well known to those skilled in the art are not shown.

The device further comprises first and second grips 30 and 40, each of which has two parallel arms 45 bearing pegs 50 (see Figs. 5c) and e)).
15

One of the grips (grip 40) is provided with a support 60 which can be moved towards or away from the other grip 30 along a single longitudinal axis by a motor (not shown). The other grip 30 is fixedly
20 mounted to an end wall 35 of the device.

The grips 30 and 40 function to receive and hold spools 70 and 80 (see Figs. 5c) and 5e)). This is achieved by pegs 50 fitting into grooves 90, thereby attaching the spools 70 and 80 to grips 30 and 40 in a manner which prevents rotation of the spools 70 and 80
25 relative to the grips 30 and 40 respectively.

Spools 70 and 80 function to hold an extensible material seeded with fibroblasts, indicated by cell seeded polylactide braid prosthesis 100.
30

This is achieved by threading opposite ends of the prosthesis 100 through apertures 110 and 120 and then rotating the spools 70 and 80 several times about axes A and B respectively so that the
35 prosthesis 100 is secured to the spools 70 and 80 by friction (see Fig. 5b).

The spools 70 and 80 can then be slotted onto grips 30 and 40 as aforesaid (see Fig. 5c) and the prosthesis 100 can be extended by causing support 60 to retract within the container so that grips 30 and 40 become increasingly spaced. Once a desired degree of extension has been achieved support 60 can be held in position by a releasable locking device (not shown) and the extended prosthesis 100 can be incubated under culture conditions for as long as desired.

10

In order that the prosthesis 100 can be easily seen a window 130 is provided formed of a transparent or translucent material. This can be used for microscopic analysis of fibroblasts growing on the prosthesis 100 in order to determine when the prosthesis 100 is ready for implantation.

15

A grooved transparent or translucent block 140 is also provided for positioning at the bottom of container 10 (see Fig. 5d). The block is sized so that groove 150 can accommodate sufficient culture medium to cover the prosthesis 100 when positioned on spools 70 and 80 with the spools 70 and 80 being held by grips 30 and 40. This enables economical amounts of culture medium to be used.

20

The materials used to form the components of the straining device are autoclavable and sterilisable with alcohol. Typically the device is operated at a temperature of 37°C and with an atmosphere of 5% CO₂.

25

30

CLAIMS

1. An implantable prosthesis which in a form prior to implantation
5 comprises a biocompatible, synthetic, substantially bioresorbable
matrix material seeded with fibroblasts.
2. A prosthesis according to claim 1 wherein the bioresorbable
matrix material comprises a polylactide, a polyglycolide, a
10 polydioxanone, a poly caprolactone, a polyhydroxybutyrate, a
polyhydroxybutyrate-co-hydroxyvalerate, a polyanhydride, a
polyorthoester, a polyorthocarbonate, a polyaminocarbonate, a
polytrimethylene carbonate or a co-polymer which incorporates
monomers from which the abovementioned polymers are formed.
15
3. A prosthesis according to claim 1 or claim 2, further comprising
a non-bioresorbable matrix material.
4. A prosthesis according to claim 3 wherein the non-
20 bioresorbable matrix material is a polyester, a polyethylene, a
polypropylene, PTFE, carbon fibre, or a composite of two or more of
the aforesaid materials.
5. A prosthesis according to any preceding claims wherein the
25 matrix further comprise one or more of the following:- proteoglycans,
glycosaminoglycans, fibronectin or its active binding domain,
growth factors, osteoinductive or osteoconductive materials.
6. A prosthesis according to any preceding claim wherein the
30 prosthesis comprises a gel in intimate contact with the bioresorbable
matrix material, the gel having fibroblasts dispersed therein.
7. A prosthesis according to claim 6, wherein the gel is a collagen
or fibrin gel.
35
8. A prosthesis according to claim 7 wherein the gel is in the form
of a coating and/or a filling.

25

9. A prosthesis according to any of claims 6 to 8, wherein the bioresorbable matrix material is polyhydroxybutyrate or a copolymer incorporating a plurality of hydroxybutyrate monomers.
- 5 10. A prosthesis according to any preceding claim wherein the matrix is flexible.
11. A prosthesis according to any preceding claim which is in the form of a fibrous member.
- 10 12. A prosthesis according to any preceding claim which is in the form of a woven, knitted, crocheted or braided member.
- 15 13. A prosthesis according to any preceding claim comprising a plurality of bioresorbable matrix materials having different rates of bioresorbtion.
14. A prosthesis according to any preceding claim, wherein the fibroblasts are non-randomly oriented.
- 20 15. A prosthesis according to claim 14 wherein the fibroblasts are substantially aligned.
- 25 16. A kit for producing a prosthesis according to claim 1 comprising a fibroblast cell source or a device adapted for extracting fibroblasts from a mammalian body and a bioresorbable matrix material.
- 30 17. A kit for producing a prosthesis according to claim 6 comprising a fibroblast cell source or a device adapted for extracting fibroblasts from a mammalian body, a bioresorbable matrix material and a polymeric gel or a composition for forming the polymeric gel.
- 35 18. A device for use in manufacturing a prosthesis according to claim 14 or claim 15, wherein the device comprises a chamber for maintaining fibroblasts in a viable condition, the chamber being

provided with means for releasably securing the matrix material and means adapted for applying strain to the matrix material along a single axis only.

5

19. A method of repairing or replacing damaged connective tissue in a human or animal, comprising incubating a biocompatible synthetic substantially bioresorbable matrix material in the presence of a suitable culture medium and of fibroblasts under suitable conditions for fibroblast seeding on or in the matrix and thereafter
10 implanting the matrix seeded with fibroblasts into a host.

20. A method according to claim 19 further comprising the step of applying strain to the matrix material when seeded with fibroblasts
15 so as to cause non-random orientation of the fibroblasts.

21. A method according to claim 19 wherein the non-random orientation is a substantial alignment of fibroblasts.

20 22. A method according to claim 20 or claim 21 wherein the fibroblasts are incorporated in a gel.

23. A method according to claim 22 wherein the gel is a collagen gel or a fibrin gel.

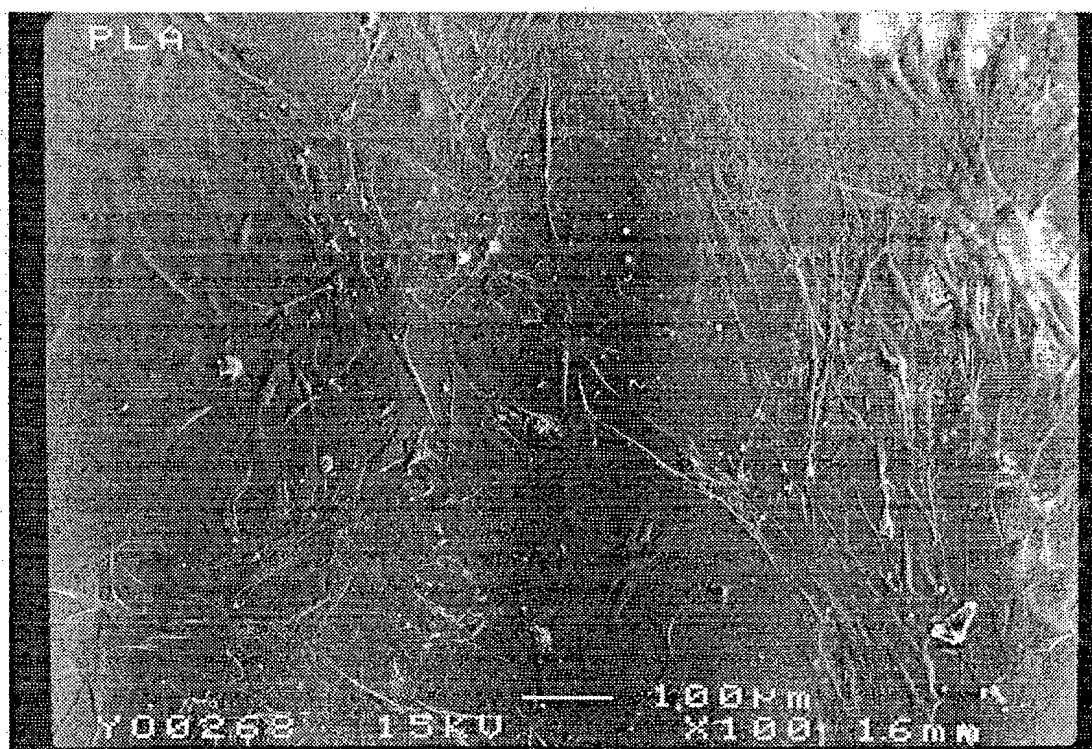
Fig. 1a

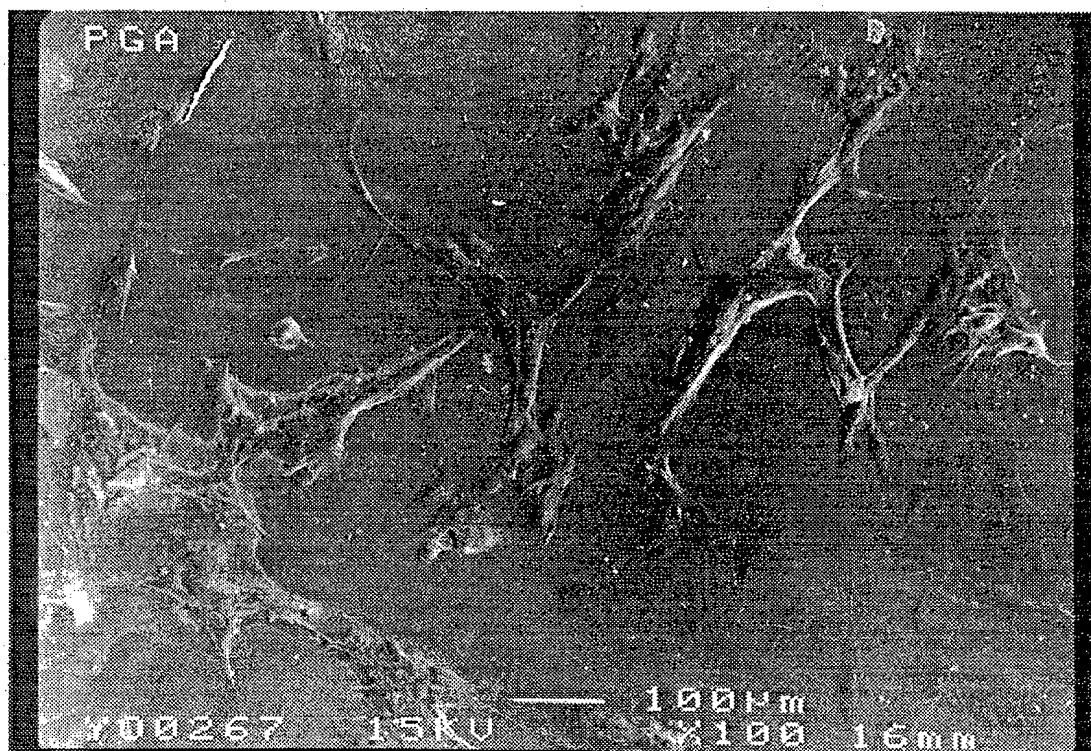
Fig 1b

Fig 1c

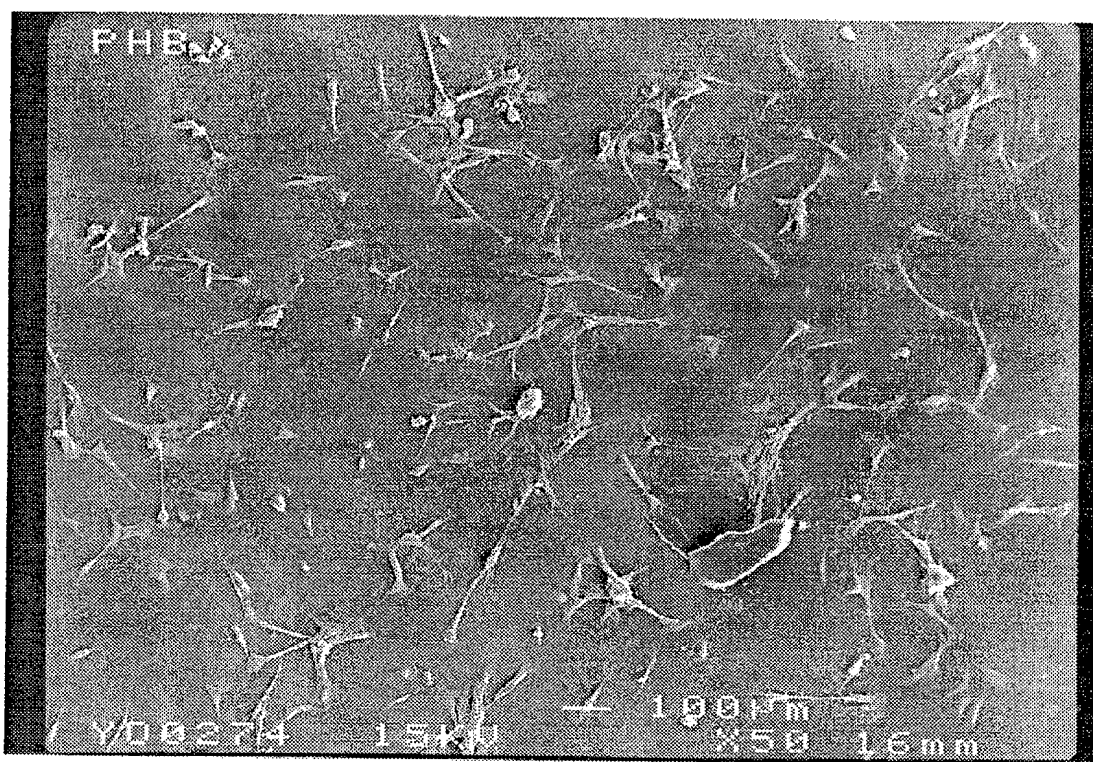


Fig 1d

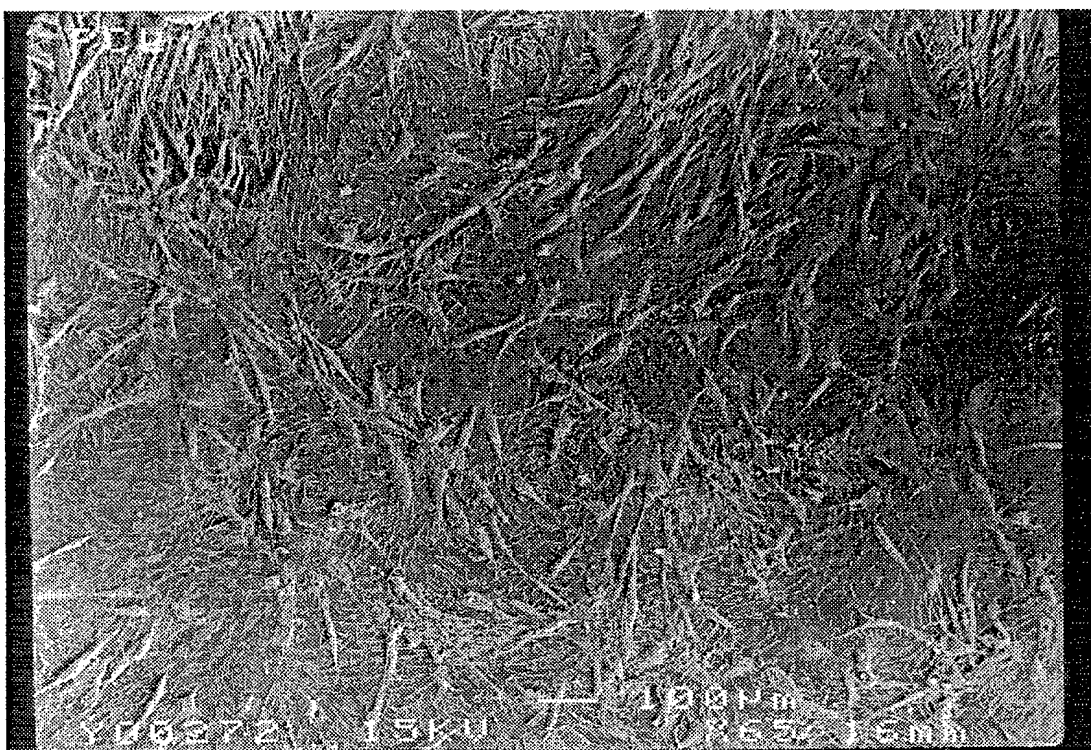


Fig 2a
Cell Proliferation on Tissue Culture Plastic

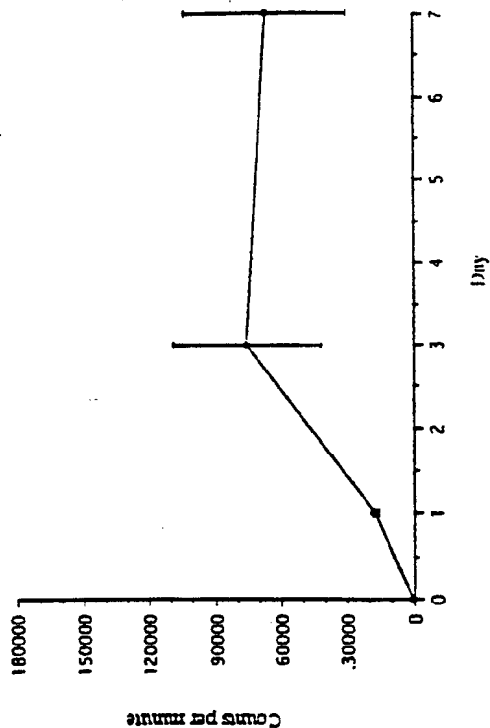


Fig 2c
Cell Proliferation on PHB

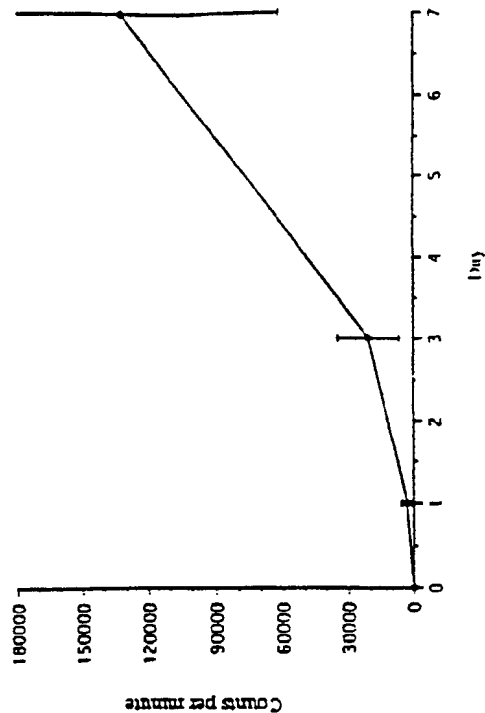


Fig 2
Cell Proliferation on a Range of Polymers

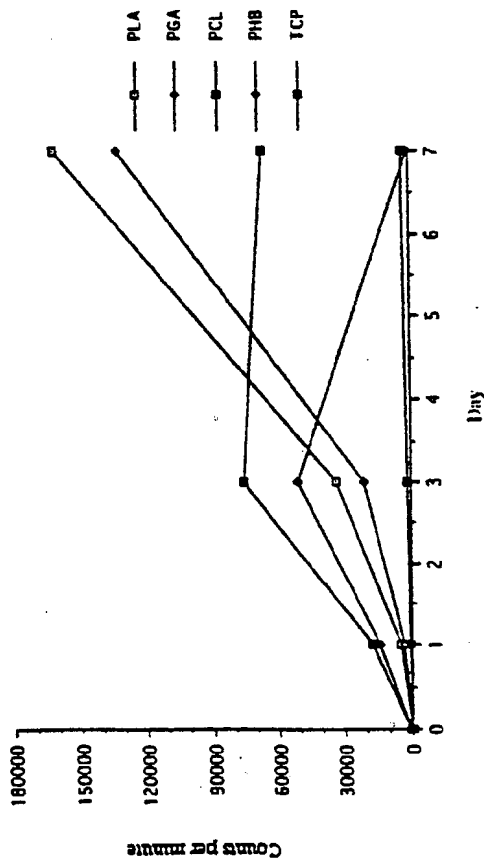
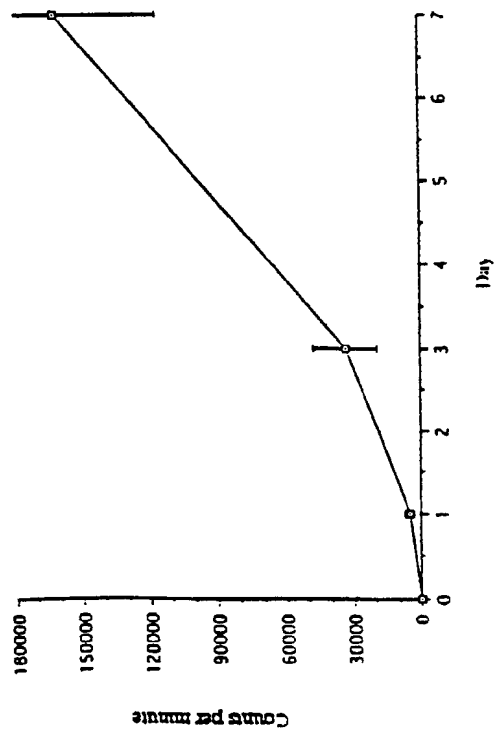
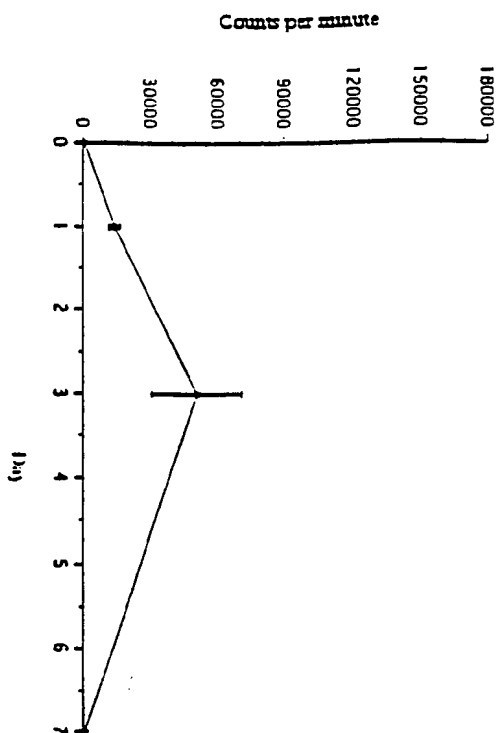


Fig 2b
Cell Proliferation on PLA

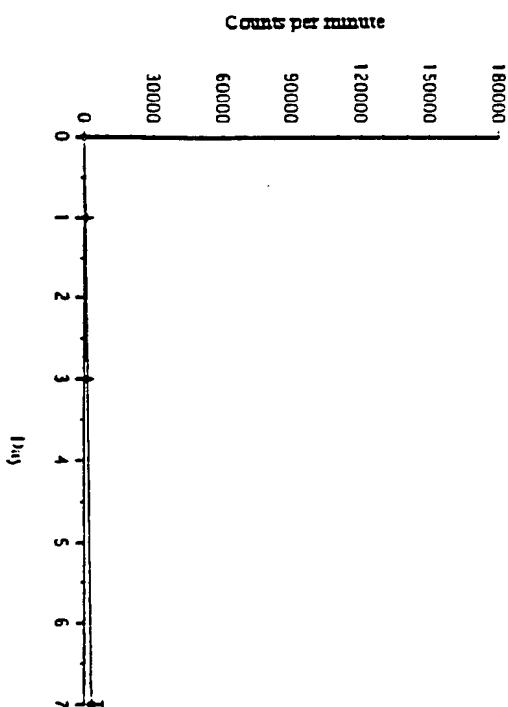


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Cell Proliferation on PGA

Fig 2d



Cell Proliferation on PCL

Fig 2e

Fig 3

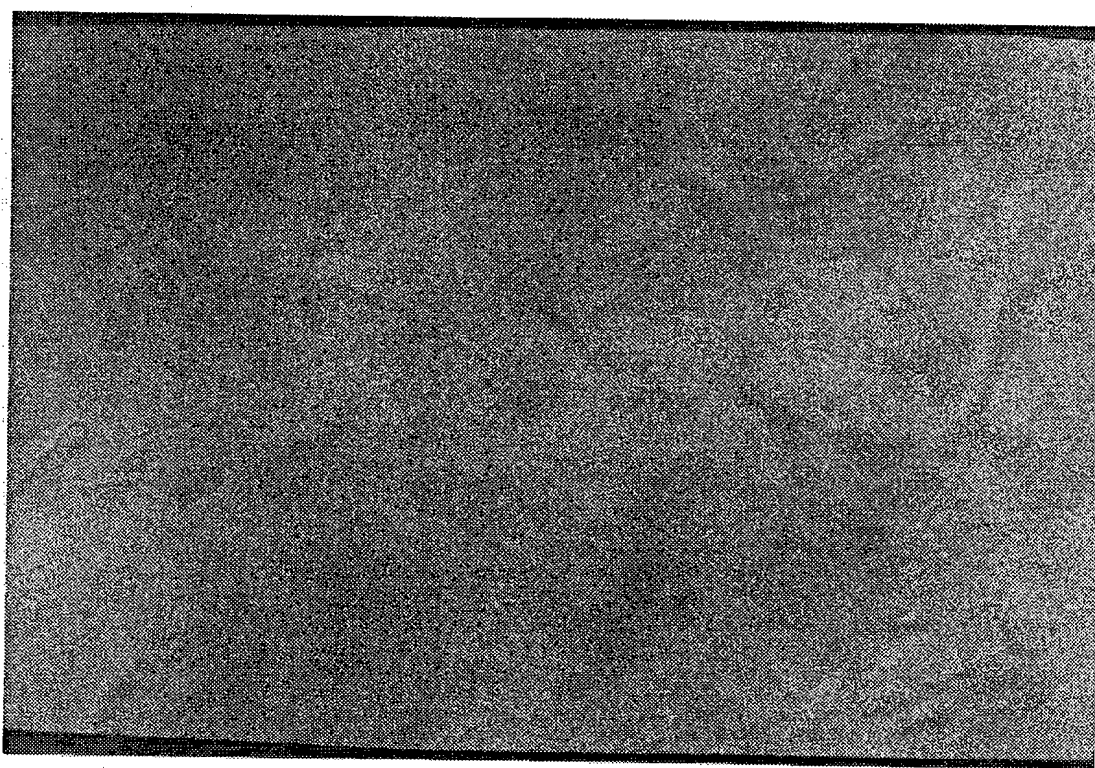


Fig 4

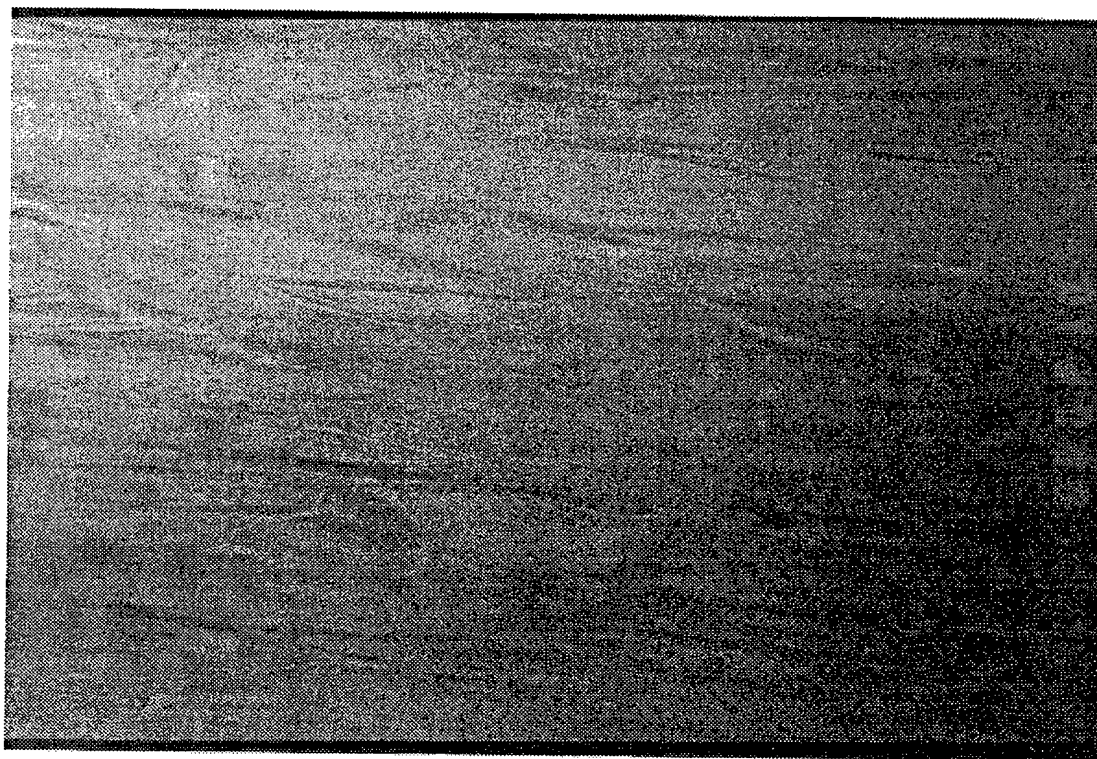
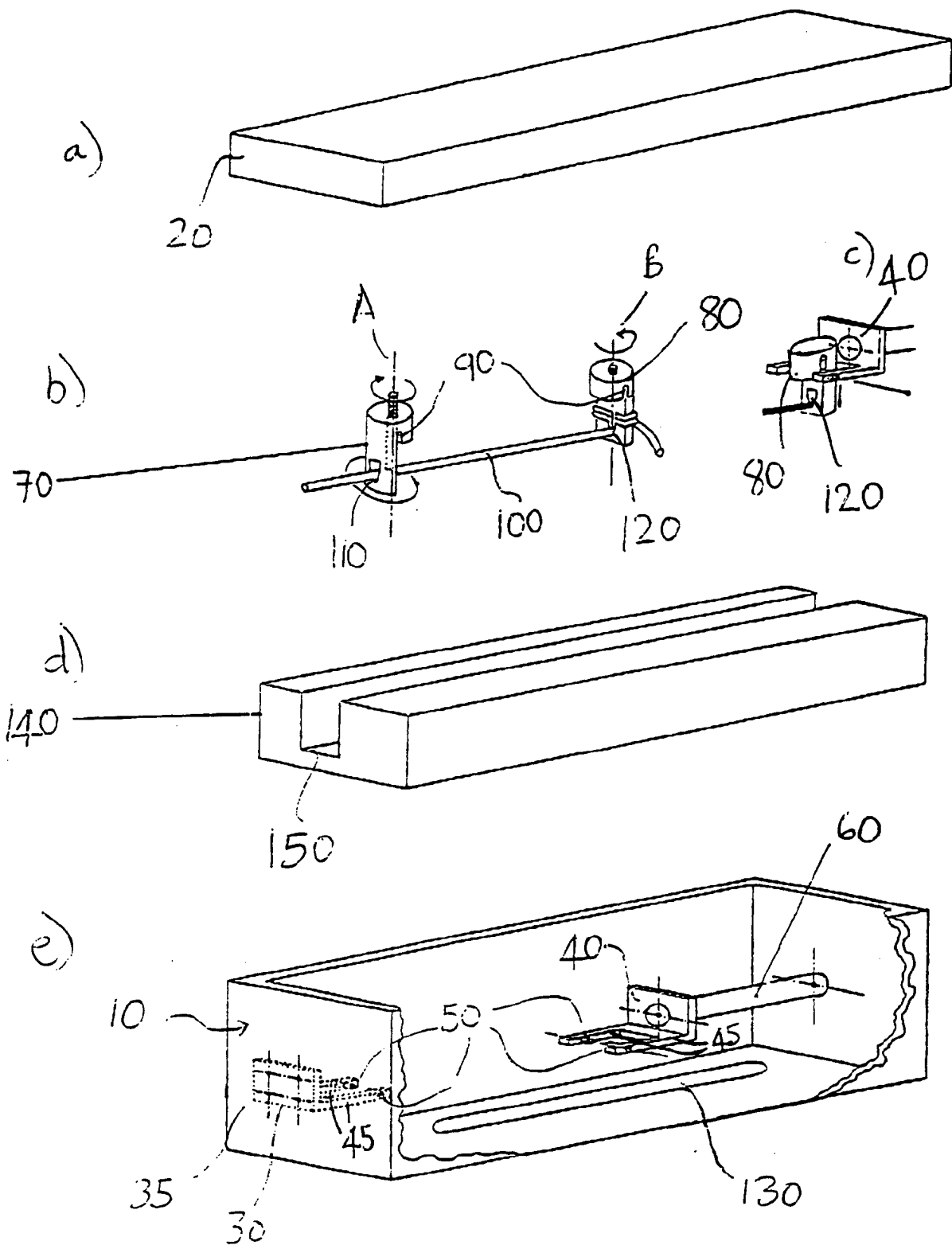


Fig 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 94/01455A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L27/00 C12M3/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L C12M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,90 12603 (VACANTI, JOSEPH, P. ET AL.) 1 November 1990 see page 6, line 9 - line 28 see page 8, line 13 - line 33 see page 11, line 23 - line 35 ---	1-15
X	WO,A,88 03785 (VACANTI JOSEPH, P. ET AL.) 2 June 1988 see page 22, line 14 - line 28; claims ---	1-3
X	WO,A,85 04185 (CAPLAN, ARNOLD, I.) 26 September 1985 see claims ---	1
Y	WO,A,92 15259 (COLORADO STATE UNIVERSITY RESEARCH FOUNDATION.) 17 September 1992 see claims --- -/--	1-23

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

12 October 1994

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INTERNATIONAL SEARCH REPORT

International application No.
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,93 07913 (CHILDREN'S MEDICAL CENTER CORPORATION.) 29 April 1993 see claims ---	1-23
P,Y	WO,A,93 19701 (BAXTER INTERNATIONAL INC.) 14 October 1993 see examples 1-3 ---	1-23
A	WO,A,93 08850 (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 13 May 1993 see page 8, line 3 - line 26; claims -----	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB94/01455

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-23
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 19-23 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/GB 94/01455

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
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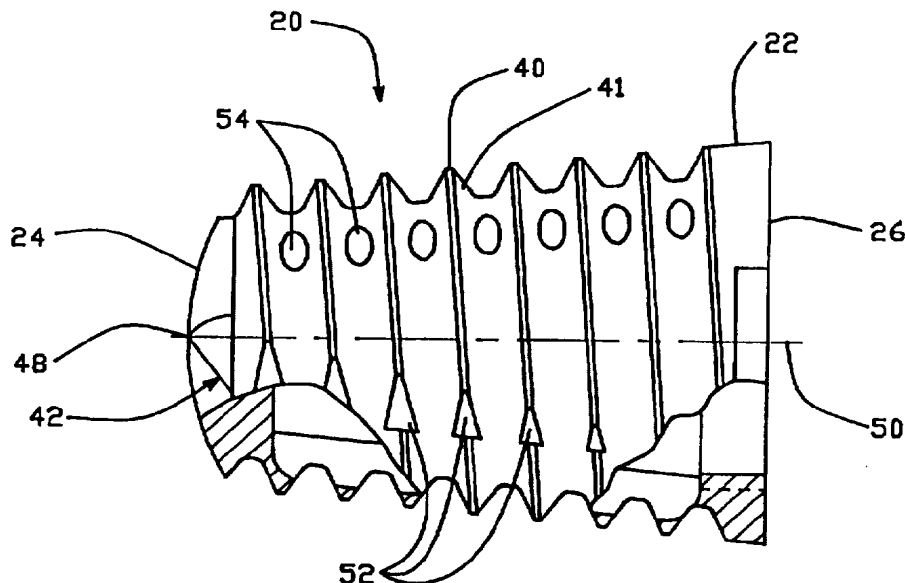
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(54) Title: CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION



(57) Abstract

A fusion cage (20) for anterior vertebral body fusion is conically shaped and includes a rounded distal end (24). A thread (40) is formed as part of the external conical surface of the fusion cage (20). The thread (40) defines one or more flutes (52) which enhance the ability of the fusion cage (20) to be self-tapping. Apertures (54, 206, 322) are defined through the fusion cage in order to provide for contact between the engaged vertebral bone structures and bone growth inducing substances packed within the fusion cage. The fusion cage (20) is introduced through an anterior procedure and maintains or increases the lordosis between adjacent vertebral bone structures.

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CONICALLY-SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION

BACKGROUND

5 Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

10 Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT,"
15 which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external
20 cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilize and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the
25 vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures.
30 The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two

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such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

Summary of the Invention

The present invention is directed to a fusion cage which has been designed to be implanted using an anterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The conically-shaped cage body is particularly advantageous for use with an anterior approach to vertebral bone structure fusion. This is due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

In a second embodiment of the present invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end with the distal end having a diameter which is smaller than the

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diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface. The flute acts as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a third embodiment of the invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end, the distal end having a diameter which is smaller than the diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and a thread formed as part of the conically-shaped outer surface. The thread allows the cage body to be inserted using an anterior approach. Due to the fact that the cage body is conically-shaped, the requirement for pretapping the vertebral bone structures to receive the fusion cage is eliminated with the fusion cage being self-tapping. Also the cage gradually spreads apart the vertebral bone structures as the cage is inserted in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided through the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

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In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures.

The method of the present invention affords access to adjacent vertebral bone structures using an anterior approach and procedure. Such anterior approach and procedure can be preferably performed laparoscopically using an introduction set including a cannula. A laparoscopic procedure is minimally invasive as the abdomen muscle tissue can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate anterior approach and procedure, also known as an anterior lumbar interbody fusion, where an incision, perhaps up to five inches long is made, through the abdomen muscle tissue. It is to be understood however that either anterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

After such access, using preferably a laparoscopic technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into

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place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used to fuse together a variety of bone structures, in addition to being fused to one bone structure and used as, for example, a base for an implant.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

Figure 1 is a partially sectional side view of an embodiment of the fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict the progressive stages in the method of inserting the fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

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Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the fusion cage of the present invention.

5 Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

10 Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Detailed Description of the Preferred Embodiment

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage
15 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes
20 an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be
25 seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28. The proximal end 26 further define first and second peripheral indentations 36, 38. These
30 peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

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A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudinal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitudinal axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the internal cavity 30. The effect of such broaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone

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structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse axis 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 millimeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium material. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80

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are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the

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fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage
5 is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior sections 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the
10 thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this
15 occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions
20 also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of
25 the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the insertion tool 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures
30 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and

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proximal ends 202, 204. A plurality of threads 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface 214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectfully. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through an anterior approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the

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use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be
5 obtained through a review of the claims and the appended figures.

It is to be understood that additional embodiments of the invention can be constructed and fall within the spirit and scope of the claims.

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We claim:

1. A fusion cage for promoting fusion with one or more bone structures comprising:

5 a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

10

2. The fusion cage of claim 1 including:

said conically-shaped cage body having a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface.

15

3. The fusion cage of claim 2 including:

said conically-shaped cage body wherein said flute extends from the distal end toward the proximal end.

4. The fusion cage of claim 2 including:

20 at least three flutes formed in the conically-shaped outer surface.

5. The fusion cage of claim 4 including:

said three flutes are equally spaced about said distal end.

25

6. The fusion cage of claim 2 including:

said flute being additionally formed in the rounded distal end.

7. The fusion cage of claim 4 including:

said three flutes being additionally formed in the rounded distal end.

30

8. The fusion cage of claim 1 including:

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said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface.

5 9. The fusion cage of claim 8 including:
at least one flute formed in the thread.

 10. The fusion cage of claim 8 including:
said conically-shaped cage body having a conically-shaped outer surface and an internal cavity; and
10 a plurality of apertures formed through the conically-shaped body which communicate said conically-shaped outer surface with said internal cavity.

 11. The fusion cage of claim 1 including:
15 said conically-shaped cage body is a right circular cone.

 12. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections,
20 said fusion cage comprising:

 a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures
25 and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace; and

30 said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer surface in

- 15 -

order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

13. The fusion cage of claim 12 including:

5 said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior interspace toward the posterior interspace.

14. The fusion cage of claim 12 including:

10 at least one flute formed in the thread.

15. The fusion cage of claim 14 including:

 said flute extends from the distal end toward the proximal end.

16. The fusion cage of claim 12 including:

15 at least three flutes formed in the thread.

17. The fusion cage of claim 16 including:

 said three flutes are equally spaced about said distal end.

18. The fusion cage of claim 13 including:

20 at least one flute being formed in the rounded distal end.

19. The fusion cage of claim 18 including:

25 three flutes being formed in the rounded distal end.

20. The fusion cage of claim 12 including:

 said conically-shaped cage body having an internal cavity; and

 a plurality of apertures formed through the conically-shaped body

30 which communicate said conically-shaped outer surface with said internal cavity.

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21. The fusion cage of claim 12 including:
said conically-shaped cage body is a right circular cone.

22. A fusion cage for promoting fusion with one or more bone
5 structures comprising:

a conically-shaped cage body having a proximal end and a distal
end, said distal end having a diameter which is smaller than a diameter of
said proximal end; and

10 said conically-shaped cage body having a conically-shaped outer
surface and at least one flute formed in the conically-shaped outer surface.

23. The fusion cage of claim 22 including:
said distal end being rounded in order to facilitate insertion relative
to one or more bone structures.

15 24. The fusion cage of claim 22 including:
said conically-shaped cage body wherein said flute extends from
the distal end toward the proximal end.

20 25. The fusion cage of claim 22 including:
at least three flutes formed in the conically-shaped outer surface.

26. The fusion cage of claim 22 including:
three flutes equally spaced about said distal end.

25 27. The fusion cage of claim 23 including:
a flute formed in the rounded distal end.

28. The fusion cage of claim 25 including:
30 said distal end being rounded in order to facilitate insertion relative
to the one or more bone structures;
and

- 17 -

said three flutes being additionally formed in the rounded distal end.

29. The fusion cage of claim 22 including:
a thread formed into said conically-shaped outer surface.

5

30. The fusion cage of claim 29 including:
said at least one flute formed in the thread.

31. The fusion cage of claim 22 including:
10 said conically-shaped cage body an internal cavity; and
a plurality of apertures formed through the conically-shaped body
which communicate said conically-shaped outer surface with said internal
cavity.

15 32. An anterior fusion cage for promoting fusion between
vertebral bone structures comprising:

a conically-shaped cage body having a proximal end and a distal
end, said distal end having a diameter which is smaller than a diameter of
said proximal end, said distal end for initial insertion between vertebral
20 bone structures from an anterior approach;

said conically-shaped cage body having a conically-shaped outer
surface and a thread with a plurality of turns formed into said conically-
shaped outer surface, and a flute formed in at least one said turns;

said conically-shaped cage body having an interior cavity; and
25 a plurality of apertures formed through the conically-shaped body
which communicate said conically-shaped outer surface with said internal
cavity.

33. The fusion cage of claim 32 including:
30 said distal end being rounded in order to facilitate insertion
between the vertebral bone structures from an anterior location towards
a posterior location.

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34. The fusion cage of claim 32 including:
said conically-shaped cage body wherein said flute extends from
the distal end toward the proximal end.

5 35. The fusion cage of claim 32 including:
at least three flutes formed in at least one of the turns.

 36. The fusion cage of claim 32 including:
three flutes equally spaced about said distal end.

10 37. The fusion cage of claim 33 including:
said flute being additionally formed in the rounded distal end.

 38. The fusion cage of claim 33 including:
15 three flutes are formed in the rounded distal end.

 39. A fusion cage for promoting fusion with one or more bone
structures comprising:

 a conically-shaped cage body having a proximal end and a distal
20 end, said distal end having a diameter which is smaller than a diameter of
said proximal end; and

 said conically-shaped cage body having a conically-shaped outer
surface and a thread formed into said conically-shaped outer surface.

25 40. The fusion cage of claim 39 including:
said distal end being rounded in order to facilitate insertion relative
to one or more bone structures.

 41. The fusion cage of claim 39 including:
30 at least one flute formed in the thread.

 42. The fusion cage of claim 41 including:

- 19 -

said flute extends from the distal end toward the proximal end.

43. The fusion cage of claim 39 including:
at least three flutes formed in the thread.

5

44. The fusion cage of claim 43 including:
said three flutes are equally spaced about said distal end.

10

45. The fusion cage of claim 40 including:
at least one flute being formed in the rounded distal end.

46. The fusion cage of claim 40 including:
three flutes being formed in the rounded distal end.

15

47. A fusion cage for promoting fusion with one or more bone
structures comprising:

a cage body having a proximal end and a distal end; and

said cage body having an outer surface and at least one flute
formed in the outer surface in order to facilitate the insertion of the fusion
cage in the one or more bone structures.

20

48. The fusion cage of claim 47 including:
said distal end being rounded in order to facilitate insertion relative
to one or more bone structures.

25

49. The fusion cage of claim 47 including:
said flute extends from the distal end toward the proximal end.

30

50. The fusion cage of claim 47 including:
at least three flutes formed in the outer surface.

51. The fusion cage of claim 50 including:

- 20 -

three flutes are equally spaced about said distal end.

52. The fusion cage of claim 48 including:
said flute being additionally formed in the rounded distal end.

5

53. The fusion cage of claim 47 including:
said cage body having a thread formed into said outer surface.

54. The fusion cage of claim 53 including:
said flute formed in the thread.

10

55. The fusion cage of claim 1 in combination with an insertion
tool, said fusion cage and said insertion tool including:

15

said proximal end having a opening which communicates with an
internal cavity;

an end cap which can fit into said opening in order to close off said
internal cavity;

said proximal end including at least one insertion tool receiving
indentation;

20

said end cap including an insertion tool receiving threaded bore; and

said insertion tool having a tang for being received in said
indentation and a threaded shaft for being received in said threaded bore.

said insertion tool for being engaged with said fusion cage for inserting
said fusion cage relative to the one or more bone structures.

25

56. The fusion cage of claim 10 including:

said apertures are elongated in order to increase the amount of
communication between the internal cavity and the one or more bone
structures.

30

57. A method for fusing together two spaced apart vertebral
bone structures which have posterior sections and anterior sections and

- 21 -

with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:

5 accessing the vertebral bone structures from the anterior sections;

 selecting a fusion cage with a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having a conically-shaped outer surface and a thread formed
10 into said conically-shaped outer surface;

15 position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

 causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2) a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

25 58. The method of claim 57 including:

 said causing step includes turning the fusion cage so that the thread formed as part of the outer surfaces and engage the vertebral bone structures in order to hold the fusion cage in place and stabilize the vertebral bone structures.

30

 59. The method of claim 57 including:

- 22 -

said causing step includes turning the fusion cage so that the thread self-taps a complementary thread in the vertebral bone structures.

60. A method of achieving a desired lordosis of the spinal column of a patient including the steps of:

5 accessing the vertebral bone structures from the anterior;
 positioning a conically-shaped fusion cage adjacent to anterior sections of the vertebral bone structures using an anterior procedure;
 urging the conically-shaped fusion cage into the disk space between
10 adjacent vertebral bone structures in a direction from the anterior to the posterior of the vertebral bone structures in order to restore a desired lordosis.

61. The method of claim 60 including the step of:

15 preparatory to the positioning step, the step selecting a conically shaped fusion cage of an appropriate size in order to achieve the desired lordosis.

62. The method of claim 60 including the step of:

20 preparatory to the positioning step, the step of selecting a conically-shaped fusion cage of an appropriate size in order to stretch the anterior longitudinal ligaments in order to stabilize the vertebral bone structures about the fusion cage.

63. The fusion cage of claim 10 including:

25 said apertures increase in size from the distal end toward the proximal end.

64. A fusion cage (1) for promoting fusion between two spaced
30 apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2)

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for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections using an anterior approach, the fusion cage comprising:

5 a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-
10 shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior interspace and the distal end is positioned in the posterior interspace.

15 65. The fusion cage of claim 64 including:

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

20

66. The fusion cage of claim 65 including:

said distal end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

25 67. The method of claim 57 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

68. The method of claim 57 including:

30 said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

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69. The method of claim 60 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

5 70. The method of claim 60 including:

said urging step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

10 71. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

15 said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

72. The fusion cage of claim 71 including:

20 said cage body having an outer surface and at least one flute formed in the outer surface.

73. The fusion cage of claim 72 including:

said cage body wherein said flute extends from the distal end toward the proximal end.

25

74. The fusion cage of claim 72 including:

at least three flutes formed in the outer surface.

75. The fusion cage of claim 71 including:

30 at least one flute formed in the rounded distal end.

76. The fusion cage of claim 71 including:

- 25 -

three flutes formed in the rounded distal end.

77. The fusion cage of claim 71 including:

5 said cage body having an outer surface and a thread formed into said outer surface.

78. The fusion cage of claim 77 including:

at least one flute formed in the thread.

10 79. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

15 a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the
20 anterior interspace larger than the height of the posterior interspace; and

said cage body having an outer surface and a thread formed into said outer surface in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior
25 interspace.

80. The fusion cage of claim 79 including:

said distal end being rounded in order to facilitate insertion of the fusion cage between the vertebral bone structures, from the anterior
30 interspace toward the posterior interspace.

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81. A fusion cage for promoting fusion with one or more bone structures comprising:

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end;

5 and

said cage body having an outer surface and at least one flute formed in the outer surface.

82. The fusion cage of claim 81 including:

10 said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

83. A fusion cage for promoting fusion between vertebral bone structures comprising:

15 a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, said distal end for initial insertion between vertebral bone structures from an anterior approach;

said cage body having an outer surface and a thread with a plurality
20 of turns formed into said outer surface,;

said cage body having an interior cavity; and

a plurality of apertures formed through the body which communicate said outer surface with said internal cavity.

25 84. The fusion cage of claim 83 wherein:

a flute is formed in at least one of said turns.

85. A fusion cage for promoting fusion with one or more bone structures comprising:

30 a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end; and

- 27 -

said cage body having an outer surface and a thread formed into said outer surface.

5 86. The fusion cage of claim 85 including:
 said cage body being conically-shaped.

 87. A fusion cage for promoting fusion with one or more bone structures comprising:
 a cage body having a proximal end and a distal end; and
10 said cage body having at least one flute formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures.

 88. The fusion cage of claim 87 including:
15 said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

 89. The fusion cage of claim 87 including:
 said flute extends from the distal end toward the proximal end.

20 90. A method for fusing together two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, with the height
25 of the anterior interspace being about the same as or larger than the height of the posterior interspace, the method comprising the steps of:
 accessing the vertebral bone structures from the anterior sections;
 selecting a fusion cage with a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a
30 diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal end positionable in the anterior

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interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace relative to the height of the posterior interspace, and said conically-shaped cage body having an outer surface and a thread formed into said outer surface;

5 position the fusion cage body adjacent to the anterior sections of the vertebral bone structures;

 causing said fusion cage to be inserted between the vertebral bone structures by moving the fusion cage from (1) a position with the distal end adjacent to the anterior section of the vertebral bone structures to (2)
10 a position with the distal end adjacent to the posterior sections and the proximal end adjacent to the anterior sections of said vertebral body structures.

 91. A fusion cage (1) for promoting fusion between two spaced
15 apart vertebral bone structures which have posterior sections and anterior sections with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior positions, and (2) for achieving a desired lordosis as the fusion cage is implanted by urging the fusion cage from the anterior sections toward the posterior sections
20 using an anterior approach, the fusion cage comprising:

 a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures
25 and with said proximal end positionable in the anterior interspace between the anterior sections of said vertebral bone structures as the conically-shaped cage body is urged using an anterior approach from an initial position where the distal end is positioned adjacent to the anterior sections to a final position where the proximal end is positioned in the anterior
30 interspace and the distal end is positioned in the posterior interspace.

 92. The fusion cage of claim 91 including:

- 29 -

said conically-shaped cage body having a conically-shaped outer surface and a thread formed into said conically-shaped outer space in order to engage the vertebral bone structures as the cage body is inserted from the anterior interspace toward the posterior interspace.

5

93. The fusion cage of claim 91 including:

said posterior end of said cage body is rounded in order to facilitate insertion between the vertebral body structures.

10

94. The method of claim 90 including:

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

95. The method of claim 90 including:

15

said causing step distracting the anterior sections more than the posterior sections, and for causing the vertebral bone structures to pivot about the posterior sections.

96. The method of claim 90 including:

20

using a laparoscopic procedure to access the vertebral bone structures and to insert the fusion cage.

97. The method of claim 90 including:

said causing step for distracting the anterior sections more than the posterior sections of the vertebral bone structures, and for causing the vertebral bone structures to pivot about the posterior sections.

25

98. A fusion cage for promoting fusion with between two spaced apart vertebral bone structures which have posterior sections and anterior sections and with a posterior interspace defined between the posterior sections and an anterior interspace defined between the anterior sections, said fusion cage comprising:

30

- 30 -

a cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than a diameter of said proximal end, with said distal end positionable in the posterior interspace between the posterior sections of the vertebral bone structures and with said proximal
5 end positionable in the anterior interspace between the anterior sections of said vertebral bone structures in order to maintain the height of the anterior interspace larger than the height of the posterior interspace.

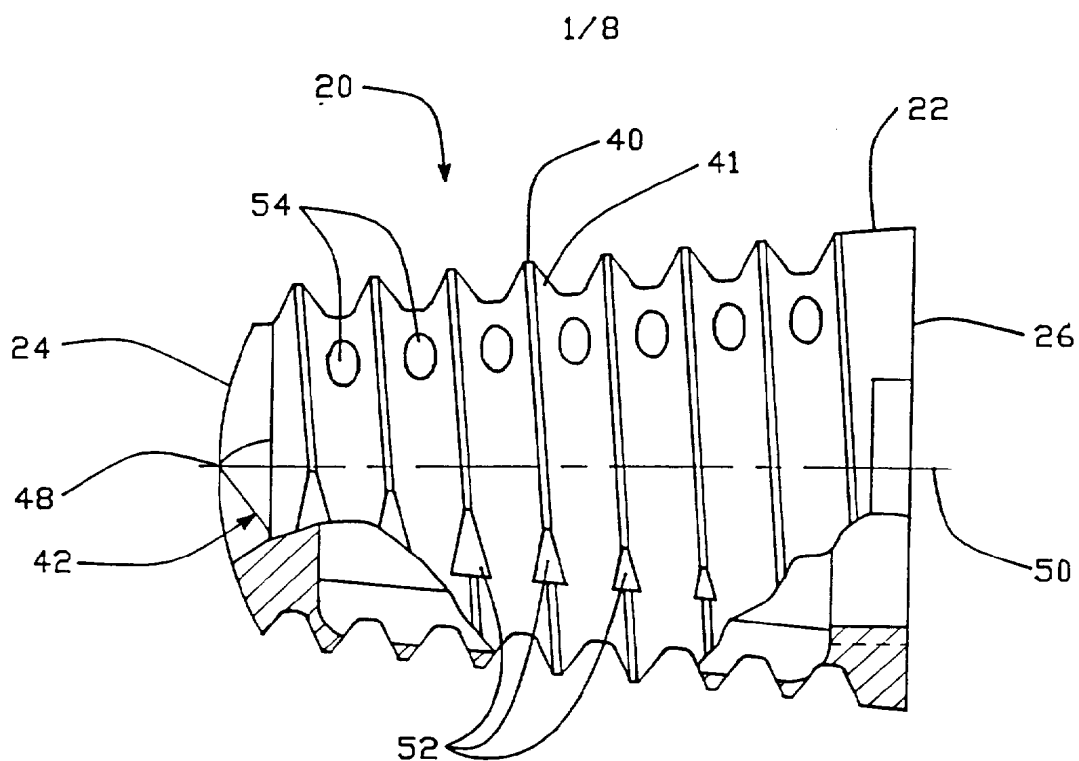


FIG.-1

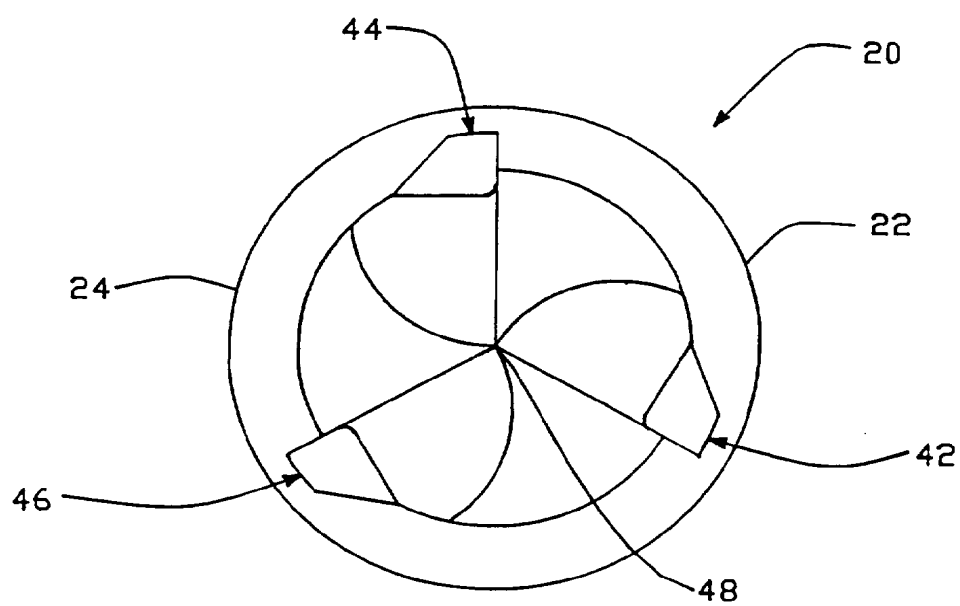


FIG.-2

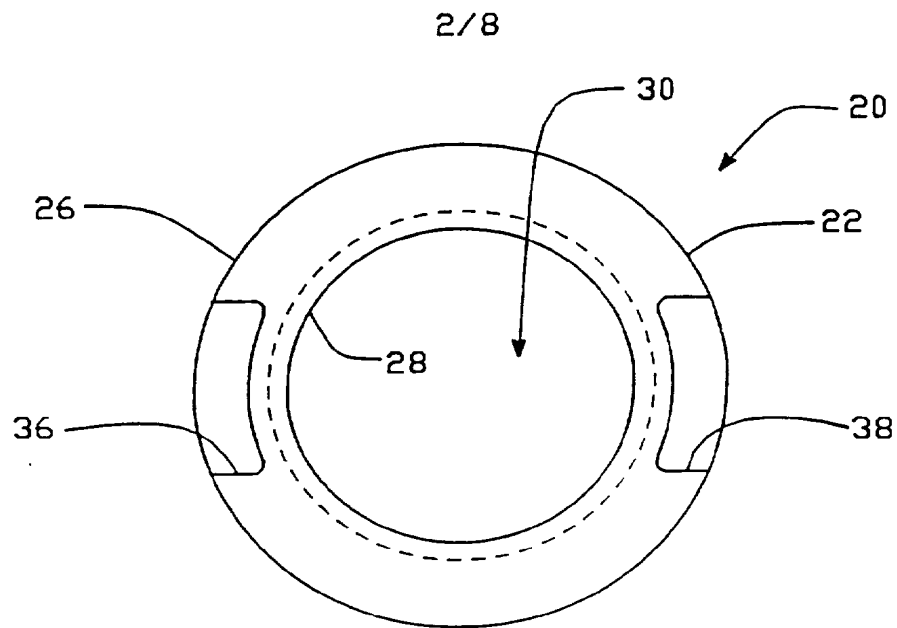


FIG.-3

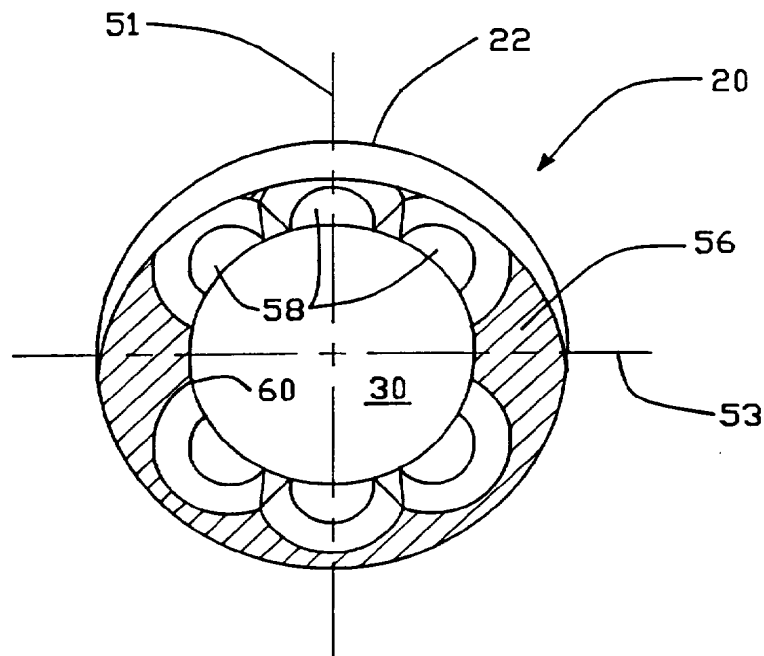


FIG.-4

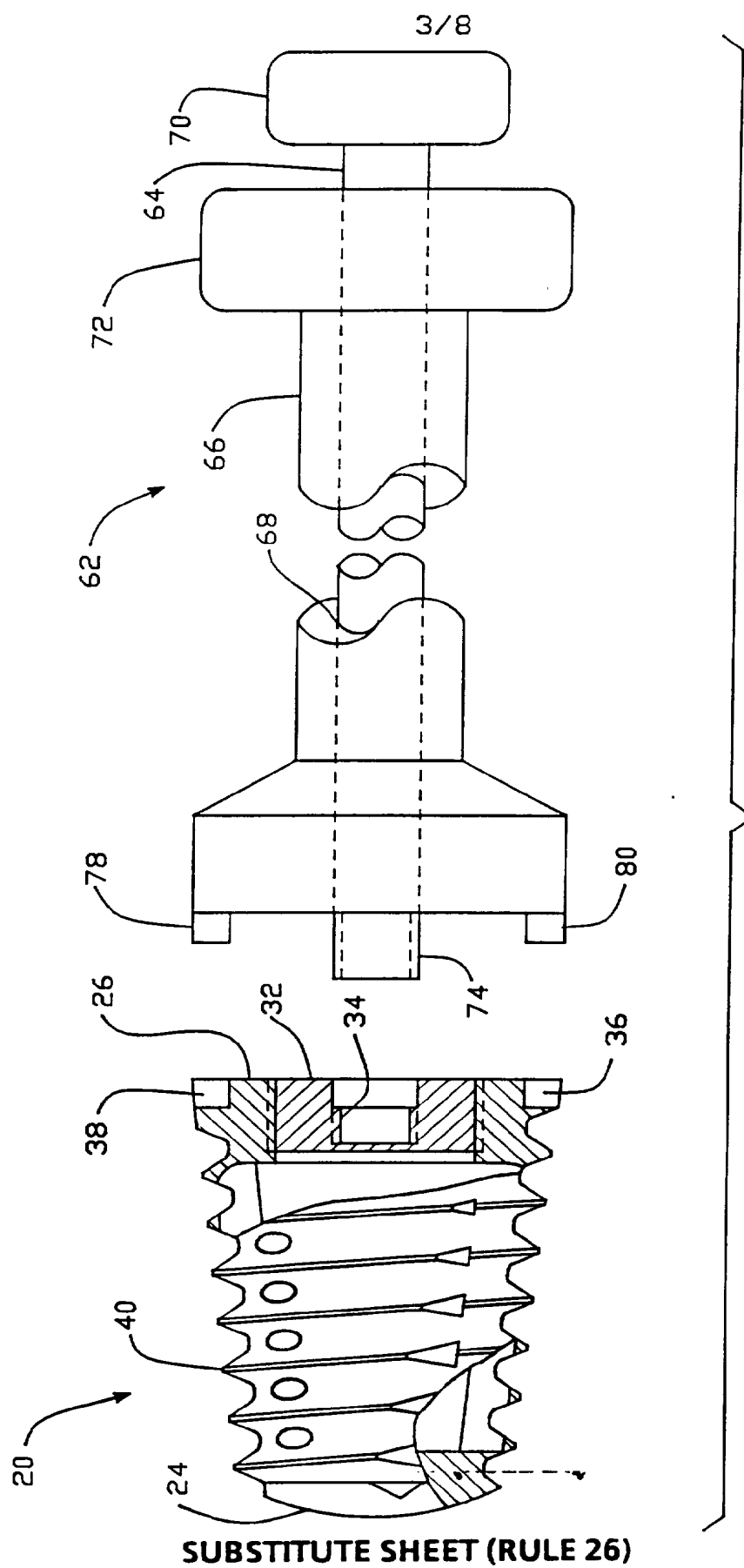


FIG.-5

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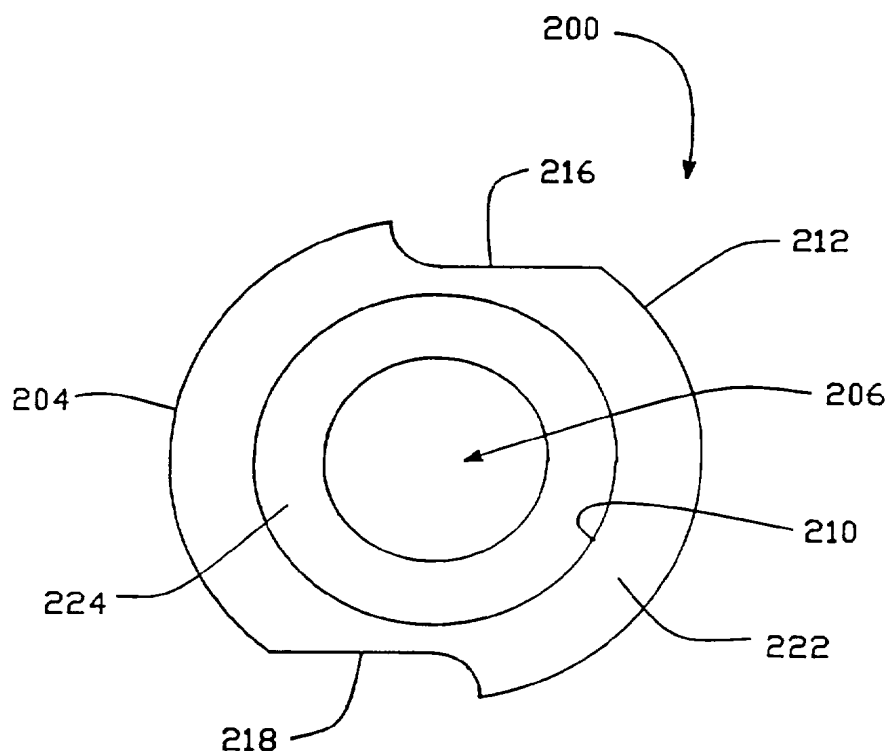


FIG.-12

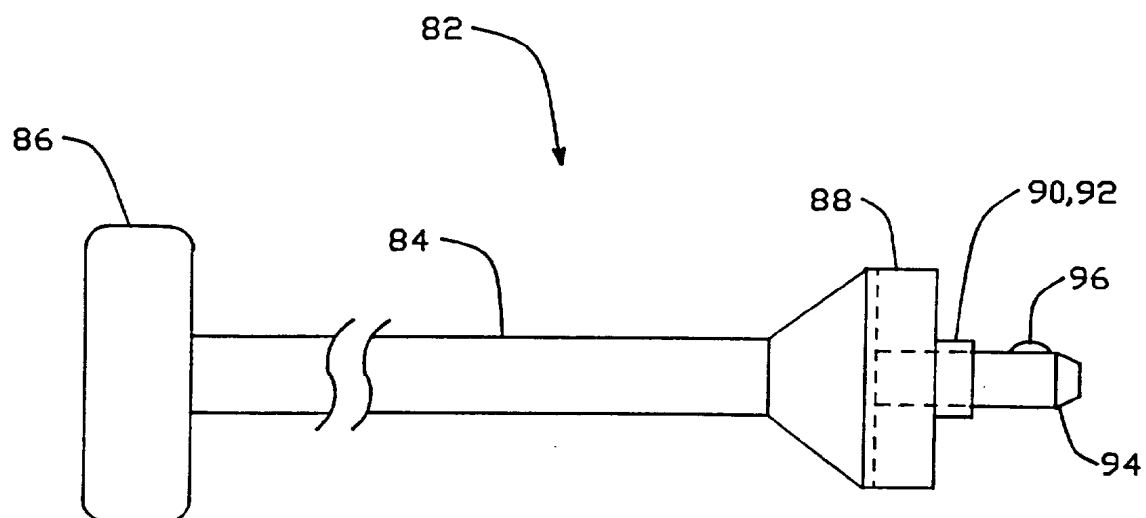


FIG.-6

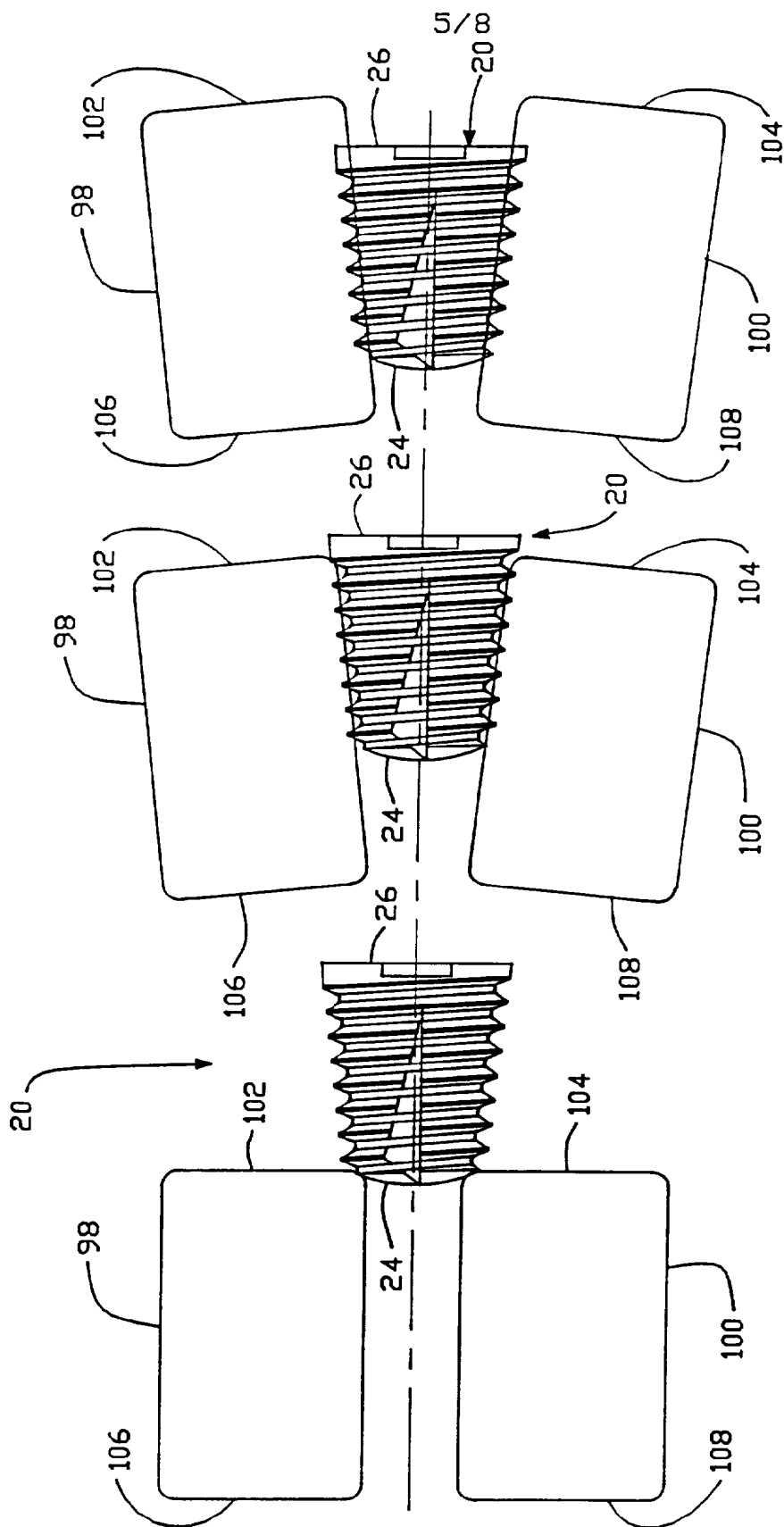


FIG.-7

FIG.-8

FIG.-9

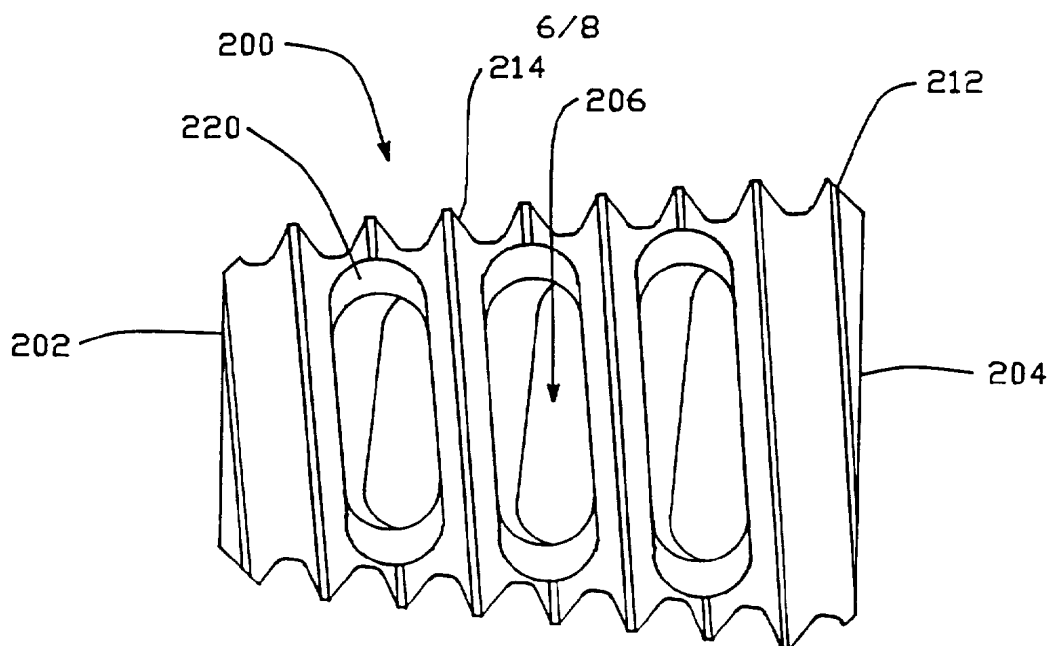


FIG.—10

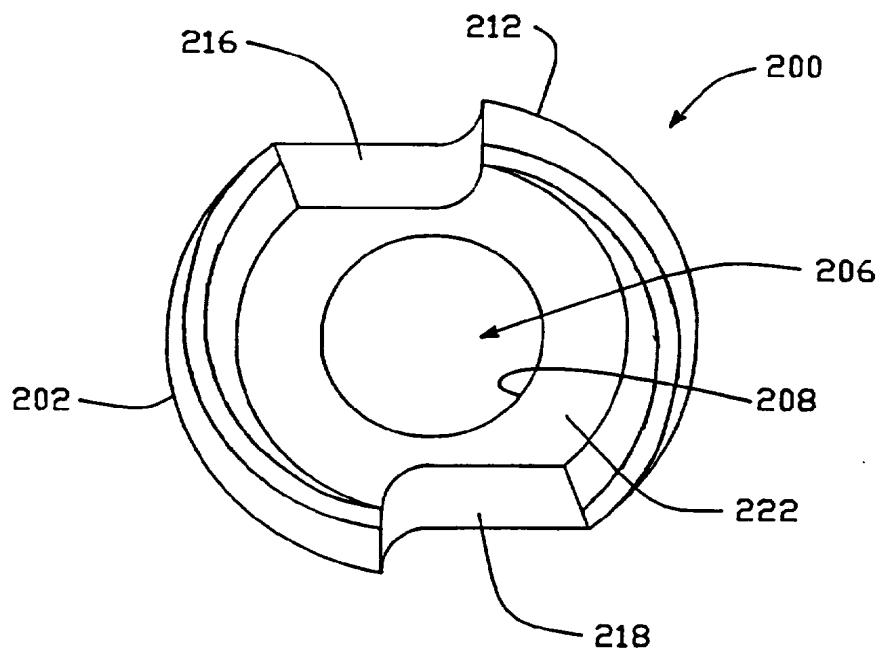


FIG.—11

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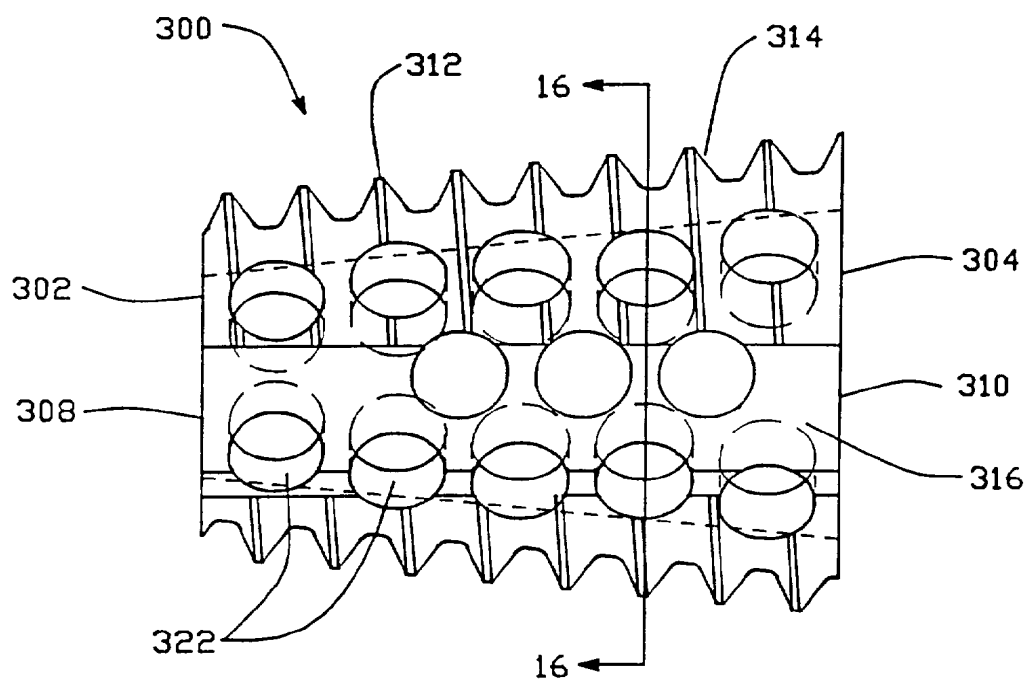


FIG.—13

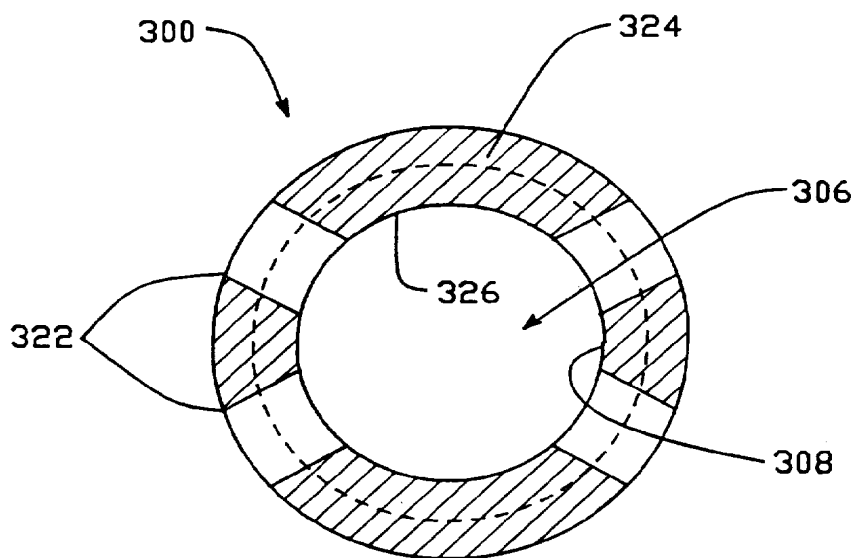


FIG.—16

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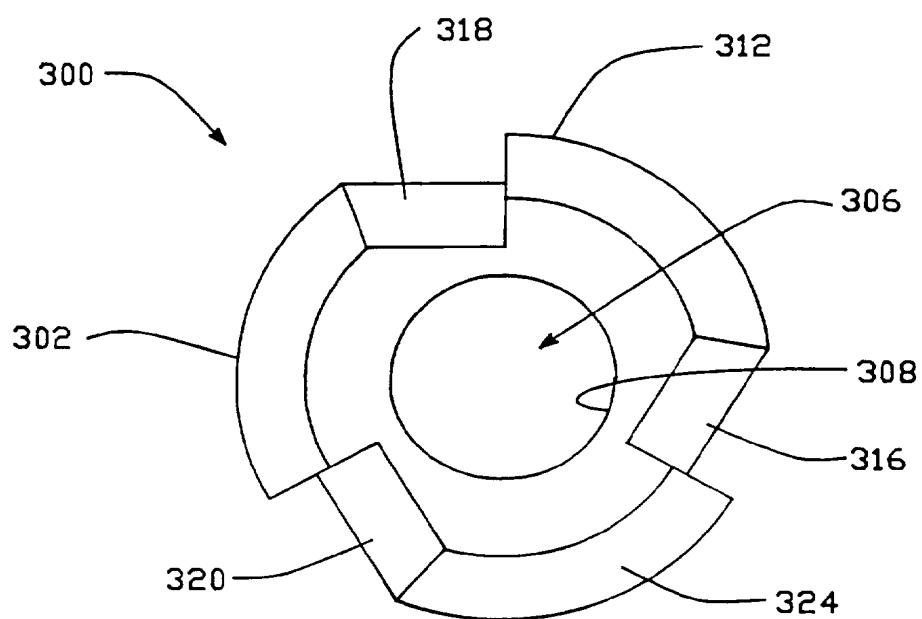


FIG.—14

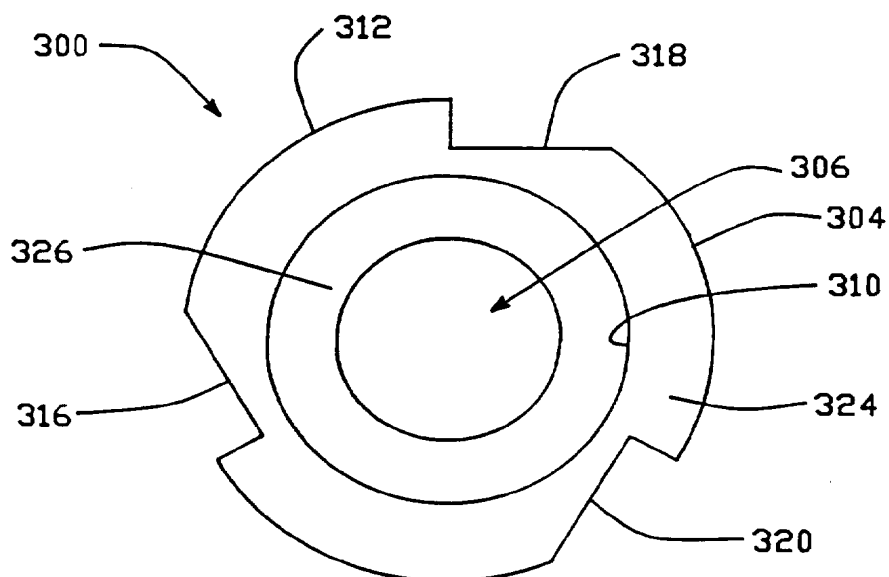


FIG.—15

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/11281

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70

US CL :606/61

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 65, 66, 72, 73, 76, 90, 104; 623/17, 16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,950,270 (BOWMAN ET AL.) 21 August 1990, see Fig. 1.	1-3, 8, 9, 11- 15, 18, 21-25, 27-30, 39-42, 45, 47-49, 52- 54, 64-66, 71- 73, 75, 77-82, 85-89, 91-93, 98 ----- 4-7, 10, 16, 17, 19, 20, 26, 31- 38, 43, 44, 46, 50, 51, 74, 76, 83, 84

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 16 OCTOBER 1995	Date of mailing of the international search report 05 DEC 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GUY TUCKER Telephone No. (703) 308-3271

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/11281

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

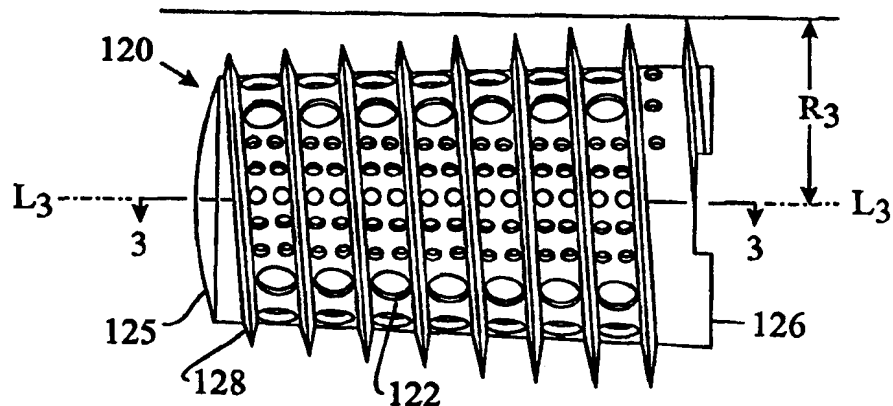
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,537,185 (STEDNITZ) 27 August 1985, see Fig. 2.	4-7, 16, 17 19, 26, 35, 36, 38, 43, 44, 46, 50, 51, 74, 76
Y	US, A, 4,484,570 (SUTTER ET AL.) 27 November 1984, see Fig. 3.	10, 20, 31-38, 83, 84
X	US, A, 4,349,921 (KUNTZ) 21 September 1982, see Fig. 4.	60
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Y		61, 62, 69

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(51) International Patent Classification ⁶: A61F 5/04	A1	(11) International Publication Number: WO 96/40020 (43) International Publication Date: 19 December 1996 (19.12.96)
(21) International Application Number: PCT/US96/08618 (22) International Filing Date: 6 June 1996 (06.06.96) (30) Priority Data: 08/480,908 7 June 1995 (07.06.95) US (71)(72) Applicant and Inventor: MICHELSON, Gary, K. [US/US]; 438 Sherman Canal, Venice, CA 90291 (US). (74) Agent: SCHELLIN, Eric, P.; Suite 704, 2121 Crystal Drive, Arlington, VA 22202 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS**(57) Abstract**

The present invention is directed to a variety of interbody spinal fusion implants (20) having at least a partially frusto-conical configuration. An external thread (28) is employed to increase implant stability and implant surface area, and for the purpose of advancing the spinal fusion implant (20) into the fusion site. The spinal fusion implants (20) of the present invention may be relatively solid or hollow and may have surface roughening to promote bone ingrowth and stability. The spinal fusion implants (20) of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation.



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THREADED FRUSTO-CONICAL INTERBODY**SPINAL FUSION IMPLANTS**BACKGROUND OF THE INVENTIONRelated Applications

5 This application is a continuation in part of
copingding United States application Serial No. 08/396,414
filed on February 27, 1995 which is a continuation-in-part
of United States application Serial No. 08/074,781 filed on
June 10, 1993, which is a continuation in part of United
10 States application Serial No. 07/698,674 filed on May 10,
1991 which is a divisional of application Serial No.
07/205,935 filed on June 13, 1988, now United States Patent
No. 5,015,247, all of which are incorporated herein by
reference.

15 This application is also a continuation-in-part
of United States application Serial No. 08/390,131 entitled
Interbody Spinal Fusion Implants filed on February 17,
1995.

Field of the Invention

20 The present invention relates generally to
interbody spinal fusion implants, and in particular to
spinal fusion implants configured to restore and maintain
two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

25 Interbody spinal fusion refers to the method of
achieving bony bridging between adjacent vertebrae through
the disc space, the space between adjacent vertebrae
normally occupied by a spinal disc. Numerous implants to
facilitate such a fusion have been described by Cloward,
30 Brantigan, and others, and are known to those skilled in
the art. Generally, cylindrical implants offer the

advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration. In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical shape substantially along the portion of the implant in contact with the adjacent vertebrae of the spine. The spinal fusion implants of the present invention have an external thread for engaging the adjacent vertebrae of the spine and have an insertion end and a trailing end. The external thread may have a variable or constant thread radius and/or a constant or variable thread height measured from the body of the implant.

The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the

implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant.

Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused. In another embodiment, where the trailing edge of the implant is larger than the leading edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading

edge to the trailing edge to facilitate insertion.

2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein
5 the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present
10 invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human
15 implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable,
20 and various ceramics or combination sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and may comprise, wholly or in part, materials capable of directly
25 participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of
30 stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

5 It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

10 It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

15 It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

20 It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

25 It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

30 It is still further another object of the present invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform

thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual lengths of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 1B is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present

invention made of a cancellous material.

Figure 1C is a cross sectional view along lines 1C--1C of Figure 1B illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 1D is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material.

Figure 1E is a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention comprising a plurality of spaced apart posts.

Figure 1F is an enlarged fragmentary sectional view along lines 1F--1F of Figure 1E illustrating the surface configuration of the implant of Figure 1E.

Figure 2 is an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body with an external thread radius and thread height that are not constant.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 5 is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of Figure 4 being implanted with a driving instrument from the posterior approach to the spinal column.

Figure 6 is a side elevational view of an

alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and truncated sides.

5 Figure 7 is an end view along line 7--7 of the spinal fusion implant of Figure 6 shown placed beside a second identical implant shown in hidden line.

10 Figure 8 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body with an irregular configuration.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 15 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is generally frusto-conical. The body 22 has an insertion end 24 and a trailing end 26. The insertion end 24 may include a tapered portion 25 to facilitate insertion of the spinal 20 implant 20. In the preferred embodiment, when the implant 20 is inserted from the anterior aspect of the spine, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

25 The implant 20 has an external thread 28 having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant 20. The outer locus of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the 30 longitudinal axis L_1 . While the major diameter of the implant 20 is substantially uniform, the external thread 28

may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser radius than the radius R_1 of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius R_1 of the remainder of the external thread 28 which is thereafter of constant radius.

The body 22 is frusto-conical substantially along the portion of the body 22 in contact with the adjacent vertebrae of the spine which allows for creating and maintaining the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread 28 of the implant 20 allows engaging the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. The greater thread height measured from the body 22 near the leading end 24 of the implant 20 provides greater purchase into the vertebral bone and again enhances the stability of the implant 20. Further, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the vertebrae to promote bone ingrowth.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion

instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to instrumentation used for inserting the implant 20.

5 Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the
10 bone in the fusion process and to provide further stability. The pores of the outer surfaces 38 are microscopic in size having a diameter that is less than 1mm, in the range of 50-1000 microns, with 250-500 microns being the preferred diameter. It is appreciated that the
15 outer surface 38, and/or the entire implant 20, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 20 may be further coated with
20 bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

25 Referring to Figure 1B, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention made of a cancellous material is shown. The cancellous material 50, similar in
30 configuration to human cancellous bone, having interstices 52 such that the outer surface 38 has a configuration as

shown in Figures 1B and 1C. As the implant of the present invention may be made entirely or in part of the cancellous material 50, the interstices 52 may be present in the outer surface 338 and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to Figure 1D, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material is shown. The mesh-like material 60 comprises strands 62 that are formed and pressed together such that interstices 64, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 38 of implant of the present invention.

Referring to Figures 1E and 1F, a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention comprising a plurality of spaced apart posts 70 is shown. The posts 70 have a head portion 72 of a larger diameter than the remainder of the posts 70, and each of the interstices 74 is the reverse configuration of the posts 72, having a bottom 76 that is wider than the entrance to the interstices 74. Such a configuration of the posts 70 and interstices 74 aids in the retention of bone material in the surface 38 of the implant and further assists in the locking of the implant into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom 76 of the interstices is wider than the entrance, the bone ingrowth cannot exit from the entrance and is locked within the interstice 74. The surface of the

implant provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

5 In the preferred embodiment, the posts 70 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 74 have a width in the range of approximately
10 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

15 In the preferred embodiment, for use in the lumbar spine, the implant 20 has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the
20 insertion end, and a root diameter at the trailing end 26 in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end 26, when said implants are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

25 In the preferred embodiment, the implant 20 has a thread radius R_1 in the range of 6 mm to 12 mm, with 9-10 mm being the preferred radius R_1 . For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred
30 length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-22 mm, with 16-18

mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body 22 of the implant 20 has a root diameter at the trailing end 26 in the range of 10-24 mm, with 18-20 mm being the preferred root diameter at the trailing end 26 when used singly, and 10-12 mm when used in pairs; a thread radius R_1 in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius R_1 when inserted singularly and 5-7 mm when inserted side by side in pairs.

Referring to Figure 2, an alternative embodiment of implant 20 is shown and generally referred to by the numeral 120. The implant 120 has a body 122 similar to body 122 of implant 120 and has an external thread 128 having a radius R_3 measured from the central longitudinal axis L_3 of the implant 120. The thread radius R_3 is not constant throughout the length of the implant 120 and the external thread 128 has a thread height that is also not constant with respect to the body 122 of the implant 120. In the preferred embodiment, the implant 120 has an external thread 128 with a radius R_3 that increases in size from the insertion end 124 to the trailing end 126 of the implant 120.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142

to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The openings 140 and 142 are macroscopic in size having a diameter that is greater than 1 mm. The large openings 140 have a diameter in the range of 206 mm, with the preferred diameter being 3.5mm; and the small openings have a diameter in the range of 1-2 mm, with 1.5 mm being the preferred diameter.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to the insertion end 124 of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap

148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 4, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frusto-conical in the reverse direction as that of implant 20 shown in Figure 1, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524 and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520 has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524. The insertion end 524 may have an anterior nose cone portion 530 presenting a tapered end to facilitate insertion.

The implant 520 has an external thread 528 having a substantially uniform radius R_6 measured from the central longitudinal axis L_6 of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_6 . It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis L_6 , such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from the body 522 that increases from the insertion end 524 to the trailing end 526.

Referring to Figure 5, a segment of the spinal

column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to initially distract apart the vertebrae V_1 and V_2 which then angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2 .

In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius R_6 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_6 .

Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape

similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L_7 . In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius R_6 measured from the central longitudinal axis L_7 that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius R_7 that is variable with respect to the longitudinal axis L_7 such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

Referring to Figure 7, an end view of the implant 620 placed beside implant 621 is shown. The implant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread 628 at

the side 670 or 672 of the implants.

Referring to Figure 8, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

The outer surface of the body 722 of implant 720 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances. If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various

embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

What is claimed is:

1. A frusto-conical interbody spinal fusion implant, comprising:

5 a body having an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, the outer locus of said external thread forming a substantially frusto-conical configuration, said implant being made of a material
10 appropriate for human implantation.

2. The implant of claim 1 in which said body has a substantially frusto-conical configuration.

3. The implant of claim 1 in which said body has a substantially cylindrical configuration.

15 4. The spinal fusion implant of claim 1 in which said trailing end is larger than said insertion end.

5. The spinal fusion implant of claim 1 in which said insertion end is larger than said trailing end.

20 6. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

7. The spinal fusion implant of claim 1 in which said implant comprises a fusion promoting material.

8. The spinal fusion implant of claim 1 in which said implant is at least in part bioabsorbable.

25 9. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

30 11. The spinal fusion implant of claim 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout at least a

portion of said implant.

12. The spinal fusion implant of claim 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread
5 radius being variable along the length of said implant.

13. The spinal fusion implant of claim 1 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

14. The spinal fusion implant of claim 1 in which
10 said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

15. The spinal fusion implant of claim 1 in which said outer surface is porous at least in part.

15 16. The spinal fusion implant of claim 1 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

17. The spinal fusion implant of claim 16 in which said internal chamber is capable of containing fusion
20 promoting material.

18. The spinal fusion implant of claim 16 in which said implant comprises a wall surrounding said internal chamber.

19. The spinal fusion implant of claim 16 in which
25 said wall has a plurality of openings passing therethrough in communication with said internal chamber.

20. The spinal fusion implant of claim 16 in which said implant has means for closing said access opening.

21. The spinal fusion implant of claim 1 in which
30 said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

22. The spinal fusion implant of claim 1 in which at least a portion of said outer surface comprises wells having at least partial walls.

5 23. The spinal fusion implant of claim 1 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said
10 first and second implants.

24. The spinal fusion implant of claim 1 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

15 25. The spinal fusion implant of claim 24 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

26. A frusto-conical interbody spinal fusion implant, comprising:

20 a body having an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, the locus of said external thread forming a substantially cylindrical configuration, said implant being made of a material appropriate for human
25 implantation.

27. The implant of claim 26 in which said body has a substantially frusto-conical configuration.

28. The implant of claim 26 in which said body has at least in part a cylindrical configuration.

30 29. The spinal fusion implant of claim 26 in which said trailing end is larger than said insertion end.

30. The spinal fusion implant of claim 26 in which said insertion end is larger than said trailing end.

31. The spinal fusion implant of claim 26 in which said implant comprises a bone ingrowth material.

5 32. The spinal fusion implant of claim 26 in which said implant comprises a fusion promoting material.

33. The spinal fusion implant of claim 26 in which said implant is at least in part bioabsorbable.

10 34. The spinal fusion implant of claim 26 having a plurality of openings capable retaining fusion promoting material.

15 35. The spinal fusion implant of claim 26 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout the length of said implant.

20 36. The spinal fusion implant of claim 26 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along at least a portion of said implant.

37. The spinal fusion implant of claim 26 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

25 38. The spinal fusion implant of claim 26 in which said external thread has a thread height measured from said body which is substantially constant along at least a portion of said implant.

30 39. The spinal fusion implant of claim 26 in which said outer surface is porous at least in part.

40. The spinal fusion implant of claim 26 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

5 41. The spinal fusion implant of claim 26 in which said internal chamber is capable of containing fusion promoting material.

42. The spinal fusion implant of claim 40 in which said implant comprises a wall surrounding said internal chamber.

10 43. The spinal fusion implant of claim 40 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

44. The spinal fusion implant of claim 40 in which said implant has means for closing said access opening.

15 45. The spinal fusion implant of claim 26 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

20 46. The spinal fusion implant of claim 26 in which at least a portion of said outer surface comprises wells having at least partial walls.

25 47. The spinal fusion implant of claim 26 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

30 48. The spinal fusion implant of claim 26 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

49. The spinal fusion implant of claim 48 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

50. An interbody spinal fusion implant, comprising:
5 a body having a substantially cylindrical configuration, an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, the locus of said external
10 thread forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

51. The spinal fusion implant of claim 50 in which said implant comprises a bone ingrowth material.

15 52. The spinal fusion implant of claim 50 in which said implant comprises a fusion promoting material.

53. The spinal fusion implant of claim 50 in which said implant is at least in part bioabsorbable

20 54. The spinal fusion implant of claim 50 having a plurality of openings capable retaining fusion promoting material.

25 55. The spinal fusion implant of claim 50 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform for at least a portion of said implant.

30 56. The spinal fusion implant of claim 50 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along at least a portion of said implant.

57. The spinal fusion implant of claim 50 in which said external thread has a thread height measured from said body which is variable along at least a portion of said implant.

5 58. The spinal fusion implant of claim 50 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

59. The spinal fusion implant of claim 51 in which
10 said outer surface is porous at least in part.

60. The spinal fusion implant of claim 51 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

61. The spinal fusion implant of claim 60 in which
15 said internal chamber is capable of containing fusion promoting material.

62. The spinal fusion implant of claim 60 in which said implant comprises a wall surrounding said internal chamber.

20 63. The spinal fusion implant of claim 60 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

64. The spinal fusion implant of claim 60 in which said implant has means for closing said access opening.

25 65. The spinal fusion implant of claim 51 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

30 66. The spinal fusion implant of claim 51 in which at least a portion of said outer surface comprises wells having at least partial walls.

67. The spinal fusion implant of claim 51 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

68. The spinal fusion implant of claim 51 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

69. The spinal fusion implant of claim 68 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

70. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, said implant being made of a material appropriate for human implantation.

71. The implant of claim 70 in which said the outer locus of said external thread forms a substantially cylindrical configuration.

72. The spinal fusion implant of claim 70 in which said insertion end is larger than said trailing end.

73. The spinal fusion implant of claim 72 in which said insertion end comprises a tapered leading portion.

74. The spinal fusion implant of claim 70 in which said trailing end is larger than said insertion end.

75. The spinal fusion implant of claim 70 in which said implant comprises a bone ingrowth material.

76. The spinal fusion implant of claim 70 in which said implant comprises a fusion promoting material.

5 77. The spinal fusion implant of claim 70 in which said implant is at least in part bioabsorbable.

78. The spinal fusion implant of claim 70 having a plurality of openings capable retaining fusion promoting material.

10 79. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout the length of said implant.

15 80. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along the length of said implant.

20 81. The spinal fusion implant of claim 70 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

25 82. The spinal fusion implant of claim 70 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

83. The spinal fusion implant of claim 70 in which said outer surface is porous at least in part.

30 84. The spinal fusion implant of claim 70 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

85. The spinal fusion implant of claim 84 in which said internal chamber is capable of containing fusion promoting material.

5 86. The spinal fusion implant of claim 84 in which said implant comprises a wall surrounding said internal chamber.

87. The spinal fusion implant of claim 84 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

10 88. The spinal fusion implant of claim 84 in which said implant has means for closing said access opening.

89. The spinal fusion implant of claim 70 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of
15 said implant.

90. The spinal fusion implant of claim 70 in which at least a portion of said outer surface comprises wells having at least partial walls.

91. The spinal fusion implant of claim 70 in which
20 said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said
25 first and second implants.

92. The spinal fusion implant of claim 70 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

93. The spinal fusion implant of claim 92 in which
30 said external thread has a thread height measured from said body which is greatest at said truncated side.

94. The spinal fusion implant of claim 1 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

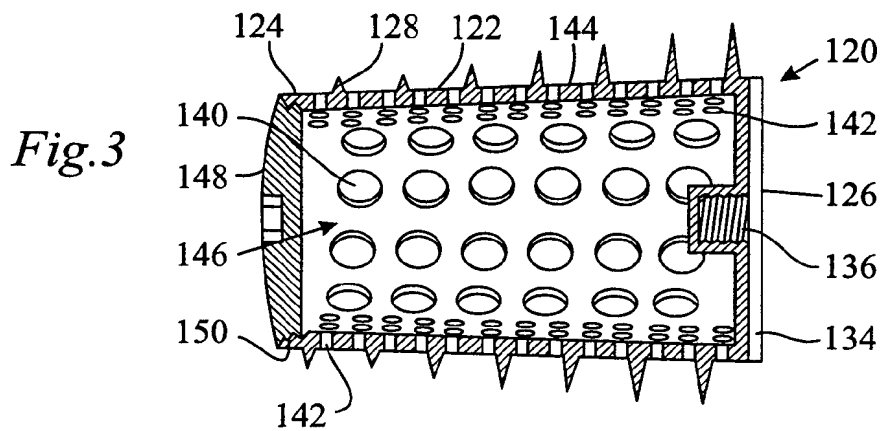
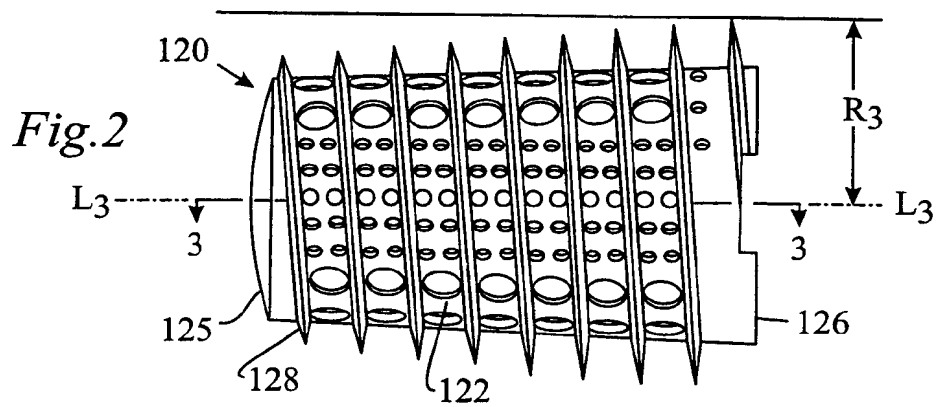
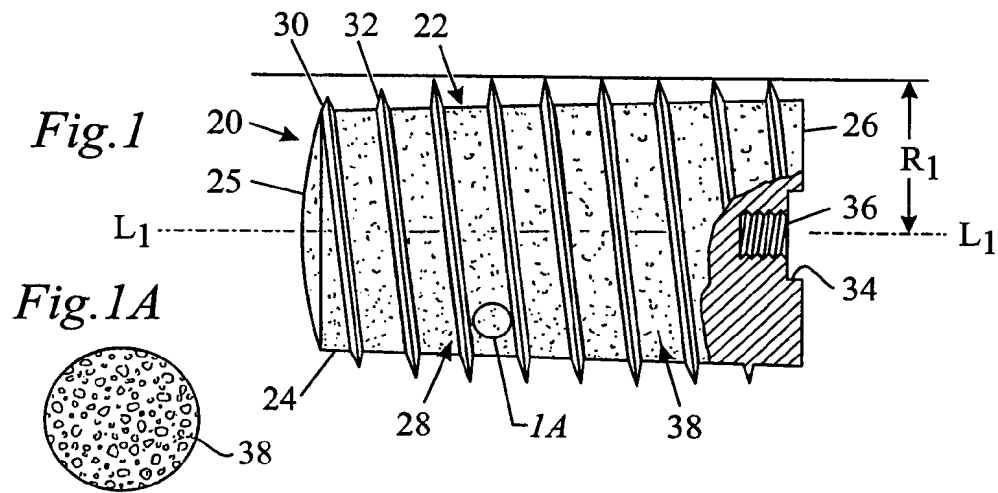
5 95. The spinal fusion implant of claim 26 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

10 96. The spinal fusion implant of claim 50 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

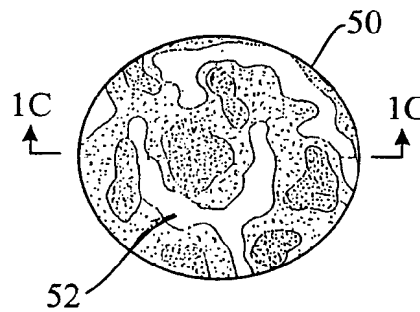
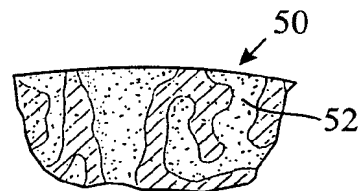
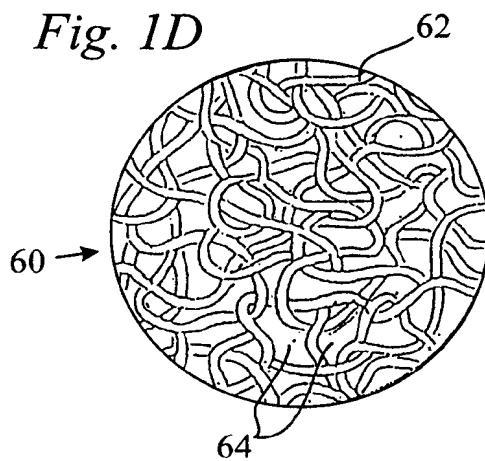
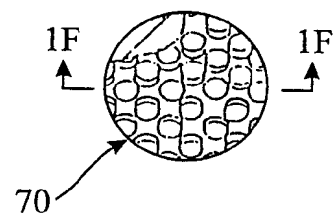
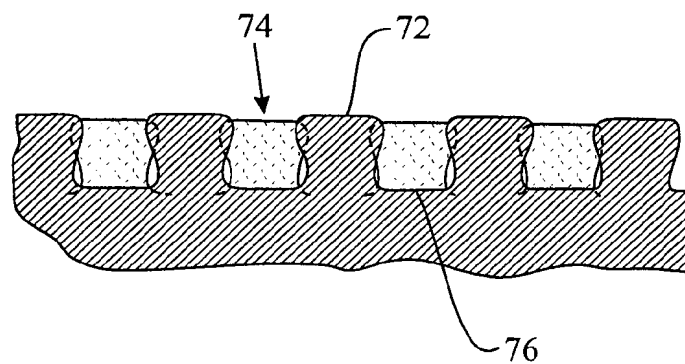
15 97. The spinal fusion implant of claim 70 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

98. The spinal fusion implant of claim 24 in which said external thread is continuous over at least a portion of said truncated side.

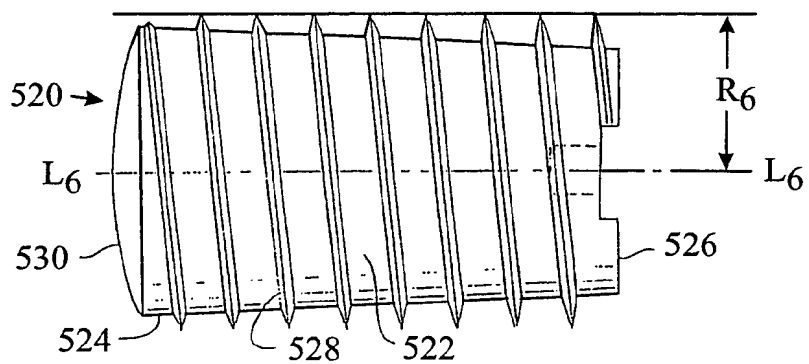
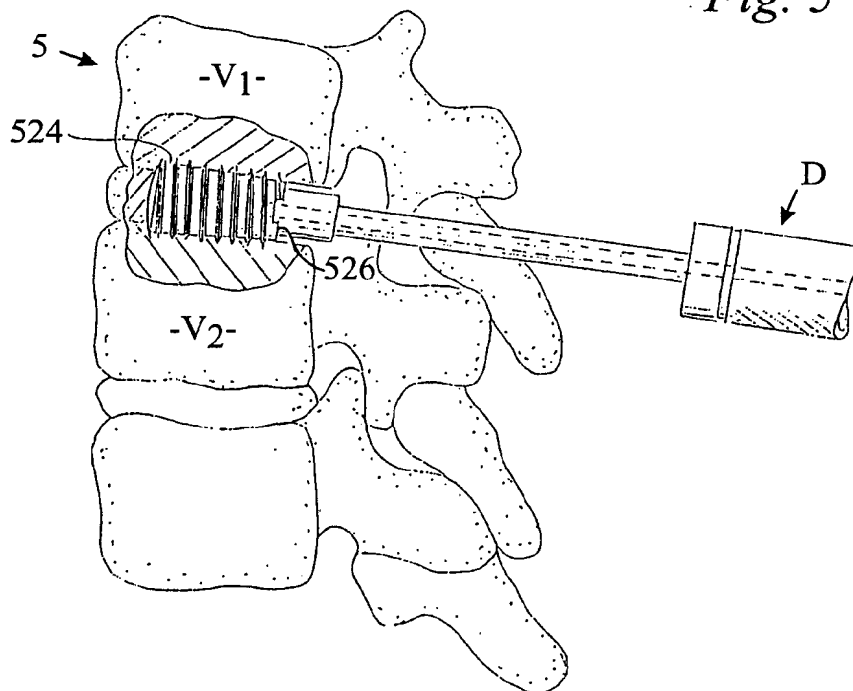
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Fig. 1B*Fig. 1C**Fig. 1D**Fig. 1E**Fig. 1F*

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Fig. 4*Fig. 5*

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Fig. 6

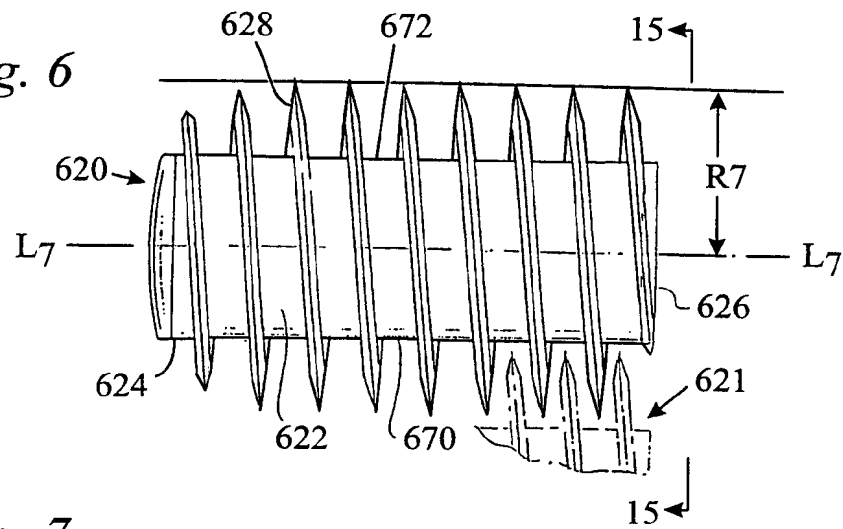


Fig. 7

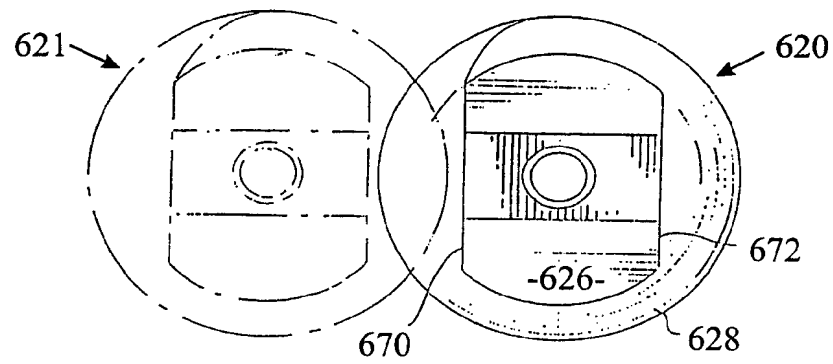
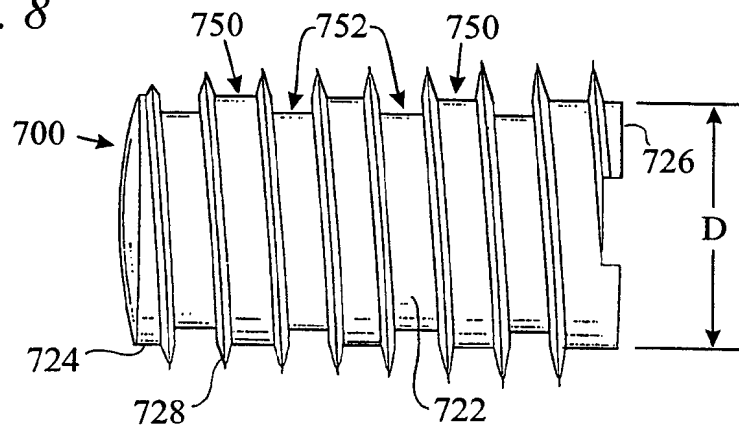


Fig. 8



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/08618**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61F 5/04

US CL :606/61; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 72-78; 623/16-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,349,921 A (KUNTZ) 21 September 1982, entire document.	1, 2, 4, 26, 27, 29, 70, 72, 73 ----- 3, 5, 8, 9, 11, 13, 22, 28-46, 53, 56-58, 71, 74, 75-90, 94-97

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

27 OCTOBER 1996

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/08618

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,961,740 A (RAY et al) 09 October 1990, entire document	6, 7, 9, 11, 14, 15-22, 31, 32, 34, 35, 39-46, 50-52, 54, 55, 59-66, 75, 76, 78, 79, 82-90, 94-97
Y	US 4,904,260 A (RAY et al) 27 February 1990, entire document.	8, 33, 53, 77



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Avec rapport de recherche internationale.

(54) Title: IMPLANT FOR SURGICALLY TREATING A VERTEBRAL ISTHMIC FRACTURE

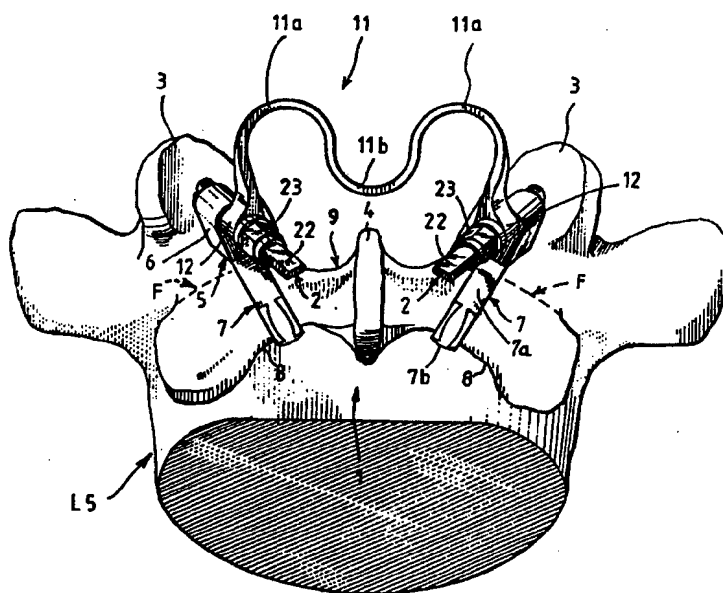
(54) Titre: IMPLANT POUR LE TRAITEMENT CHIRURGICAL D'UNE FRACTURE ISTHMIQUE VERTEBRALE

(57) Abstract

An implant including a pair of screws (2) for screwing into respective vertebral facets (3), a pair of hooks (5) each consisting of a body (6) and a blade (7), said body having a through-bore for the screw, and said bore having a longitudinal axis at a suitable angle to the central longitudinal plane of the blade (7) such that the hook blade can suitably engage the posterior arch (9), a resilient connecting member (11) for holding apart the two screws and urging the blades (7) against the edges of the posterior arch, and nuts (23) for locking the connecting member and the hooks to the screws. Said implant takes up less space on the posterior side than known implants and thus avoids undesirable lumps under the skin, and the above-mentioned angular offset enables the hooks to engage a suitable area on the edges of the posterior arch, so that the surgeon is not required to perform preliminary cutting of the posterior arch.

(57) Abrégé

Cet implant comprend une paire de vis (2) destinées à être vissées chacune dans une facette vertébrale (3), une paire de crochets (5) constitués chacun d'un corps (6) et d'une lame (7), le corps étant percé d'un alésage de passage de la vis, dont l'axe longitudinal forme avec un plan longitudinal médian de la lame (7) un angle approprié pour permettre un appui convenable de la lame du crochet sur l'arc postérieur (9), un organe (11) de liaison élastique agissant en distraction entre les deux vis, et appliquant les lames (7) contre les bords de l'arc postérieur, et des écrous (23) de blocage de l'organe de liaison et des crochets sur les vis. Cet implant présente un encombrement postérieur réduit par rapport aux implants connus et évite donc ainsi des saillies gênantes sous la peau, et, grâce au décalage angulaire précité, les crochets peuvent prendre appui sur une zone adéquate des bords de l'arc postérieur sans qu'il soit nécessaire au chirurgien de tailler au préalable l'arc postérieur.



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- 1 -

Implant pour le traitement chirurgical d'une fracture isthmique vertébrale".

La présente invention a pour objet un implant pour le traitement chirurgical d'une fracture isthmique vertébrale. Plus précisément l'invention concerne le traitement chirurgical du spondylolisthésis du premier degré et de la spondylolyse par fracture isthmique.

Si cette anomalie rachidienne est très souvent découverte chez de jeunes patients dont la moyenne d'âge est de 11,5 ans et dont le pourcentage de cas le plus élevé (environ 73%) se trouve chez les jeunes filles, ce même traitement se rencontre aujourd'hui également chez les adultes. Ainsi, il est estimé que 5 à 7% de la population blanche présente une spondylolyse affectant le plus souvent la vertèbre L5, parfois L4 ou L3, et avec un listhésis dans seulement 60% des cas.

Il est généralement aujourd'hui admis que la spondylolyse est la conséquence d'une surcharge mécanique de l'isthme avec fracture de fatigue secondaire. Au stade préliminaire de cette évolution, on rencontre assez souvent une sclérose de l'isthme comme signe prémonitoire de la spondylolyse.

Cette surcharge résulte de deux mécanismes :

1 - Une hyperlordose (fonctionnelle, acquise ou congénitale) conduisant à un effet "casse-noisette" par hyperpression du processus articulaire cranial sur l'isthme, la fréquence de la spondylolyse dans les disciplines sportives conduisant à une hyperlordose (en particulier les gymnastes).

2 - La spondylolyse se rencontre aussi en l'absence d'une hyperlordose et est due, dans ce cas, à une anomalie de développement de la région isthmique : l'angle formé par la direction de la colonne articulaire inférieure de L5 par rapport au plan postérieur du corps vertébral est en moyenne de 168° à la naissance et de 145° chez l'adulte

européen. Il arrive que cette incurvation de 18 à 28° ne se produise pas en cours de développement. Il en résulte également un effet de "casse-noisette" de la part du processus articulaire proximal.

5 De fait, tant que cette surcharge articulaire existe sur l'isthme, cette fracture ne peut se consolider spontanément (pseudarthrose) et peut entraîner des douleurs lombaires, parfois sciatiques ou neurales par compression des éléments nerveux par le tissu au contact
10 de la pseudarthrite. La fracture nécessite alors un traitement chirurgical au stade de la pseudarthrose.

Préalablement à toute intervention chirurgicale, un traitement probatoire doit être effectué. Les différents traitements possibles sont les suivants : physio-
15 thérapie, thérapeutiques médicamenteuses, infiltrations locales, gymnastique lombaire, corset. Cependant, malgré ces traitements certains cas demandent une indication opératoire.

20 On connaît actuellement plusieurs techniques de réparation isthmique associant une greffe osseuse et une instrumentation qui sont les suivantes :

- La première technique consiste à reconstruire la rupture des isthmus en insérant une vis dans la fracture. Ce procédé présente l'avantage de la simplicité, mais
25 aussi des inconvénients sérieux : la vis diminue l'interface osseuse au niveau de la rupture, ce qui peut conduire à un nombre important de pseudarthrose. De plus, il exige une immobilisation externe post-opératoire avec port d'un corset par le patient et enfin on observe des ruptures des
30 vis.

- La seconde technique consiste à combiner les vis avec des fils métalliques qui retiennent les transverses avec les lames postérieures. On réalise ainsi une fixation

plus stable, améliorant la guérison des ruptures. En revanche, ce procédé est compliqué et ne permet pas d'éviter des ruptures de vis. Chez l'adulte, la plupart (90%) des interventions faites sur lyse isthmique sont actuellement des arthrodèses plus ou moins étendues selon l'état des disques. Ceci signifie qu'on réalise des appuis sur les deux vertèbres voisines de la vertèbre fracturée, ce qui constitue un inconvénient évident puisque ces vertèbres ne sont pas endommagées.

- Selon une autre technique connue, l'isthmus est reconstruit par une vis insérée dans la façade supérieure et par un crochet positionné sur la lame de l'arc vertébral, la vis et le crochet étant dans le même plan médian général. Un ressort hélicoïdal est enfilé sur la vis derrière le crochet et mis en compression contre le crochet par un écrou, un second écrou vissé contre le premier assurant un contre blocage pour s'opposer à tout desserrage du premier écrou. Deux dispositifs identiques sont ainsi montés sur les facettes et les bords correspondants de l'arc postérieur de la vertèbre.

On obtient ainsi une fixation qui, quoique de volume relativement réduit, reste encore assez encombrante par la saillie en arrière de l'arc postérieur constituée par les deux écrous, le crochet et le ressort. Ces parties saillantes se traduisent par des proéminences gênantes sous la peau au niveau des épineuses. Ces proéminences sont accentuées par le fait que le corps du crochet est positionné en appui sur l'arc postérieur relativement près de l'épineuse.

Un second inconvénient de ce type d'implant provient du fait que la compression du ressort n'est pas maîtrisée par le chirurgien, ce qui signifie que celui-ci peut comprimer trop ou pas assez ce ressort. Dans tous les

cas, le ressort applique une charge axialement sur le crochet, qui presse les deux parties fracturées l'une contre l'autre. Lorsque la soudure de ces deux parties est terminée, le crochet ne peut plus être déplacé par la
5 poussée du ressort et est donc bloqué. Par contre le ressort reste toujours comprimé et applique donc sa charge sur les écrous, ce qui à la longue provoque un arrachement de la vis de l'os de la facette, dû à une poussée axiale du dit ressort sur la vis de sorte que la vis recule. En
10 fait la vis recule alors de deux façons, d'une part sous l'effet du ressort, et aussi parce qu'elle est libre en rotation, ce mouvement de rotation étant provoqué par les vibrations dans le corps du patient au cours de son activité. La vis tend alors à sortir plus ou moins complè-
15 tement de la facette de la vertèbre, de sorte que la fracture du patient est ressoudée, mais avec une vis qui n'est plus maintenue en place et va donc se déplacer de la distance nécessaire à la décharge du ressort. Il peut en résulter une saillie importante au niveau de la peau du
20 patient, qui nécessite une seconde intervention chirurgicale pour enlever l'implant.

La vis peut du reste également reculer alors que la soudure des deux bords de la fracture n'est pas terminée, en fonction de la résistance plus ou moins grande
25 des vis à l'arrachement.

Pour réduire ce risque, le chirurgien impose au patient de ne pas s'asseoir pendant 3 mois ce qui nécessite un lit médical surélevé et une rehausse de toilette à domicile tout en portant un corset. Chez l'enfant ce
30 type d'intervention se révèle assez satisfaisant, mais par contre de nombreux échecs sont rencontrés chez les adultes en raison des efforts appliqués.

Un autre inconvénient de cette technique connue

réside dans le fait que le chirurgien est obligé de tailler l'arc postérieur pour offrir une surface d'appui suffisante au crochet, à l'emplacement prévu pour celui-ci. En effet, à cet endroit, et à défaut d'une entaille appropriée, l'arc postérieur n'offrirait pratiquement qu'une zone d'appui limitée à un angle du crochet.

Enfin une autre technique connue dite "CD" (Cotrel-Dubousset), consiste à reconstruire l'isthmus par une vis insérée dans le pédicule et un crochet positionné sur la lame de l'arc postérieur, la vis et le crochet étant reliés par une tige. Ce montage est très stable, mais présente l'inconvénient d'être relativement volumineux, compliqué et onéreux.

L'invention a donc pour but de proposer un implant agencé de manière à éviter les inconvénients des différentes réalisations ci-dessus, notamment ayant un encombrement postérieur réduit.

Conformément à l'invention, l'implant pour le traitement chirurgical d'une fracture isthmique vertébrale comprend :

- un premier sous-ensemble et un second sous-ensemble comportant chacun un élément adapté pour être fixé à une partie antérieure de la vertèbre fracturée d'un côté d'une épineuse de cette vertèbre, et un organe adapté pour être fixé à une partie postérieure de la vertèbre, cet organe étant associé à l'élément précité, et les deux sous-ensembles étant orientés suivant des axes divergents de part et d'autre de l'épineuse,

- un organe de liaison entre lesdits premier et second sous-ensembles, monté de manière à pouvoir rapprocher l'un de l'autre ledit élément et ledit organe de chaque sous-ensemble,

- et chaque sous-ensemble est pourvu de moyens de

retenue aptes à éviter la dissociation desdits éléments et desdits organes adaptés pour être fixés à une partie postérieure de la vertèbre.

5 Selon un mode de réalisation de l'invention, l'organe de liaison est élastique, et agencé pour développer sur lesdits éléments des forces de distraction dirigées suivant les directions axiales des éléments et qui tendent à appliquer contre le bord d'un arc postérieur lesdits organes fixés à ladite partie postérieure de la vertèbre.

10 Suivant un mode de réalisation préféré lesdits éléments destinés à être fixés à la partie antérieure de la vertèbre sont des vis adaptées pour être vissées dans les facettes vertébrales, lesdits organes destinés à être fixés à une partie postérieure de la vertèbre sont des crochets monopièce comprenant chacun un corps et une lame, 15 le corps étant percé d'un alésage de passage de la vis associée, et l'alésage du corps des crochets a un axe longitudinal qui forme avec un plan longitudinal médian de la lame un angle approprié pour permettre un appui convenable de la lame du crochet sur un bord correspondant de l'arc postérieur de la vertèbre. 20

Le fait de décaler angulairement l'axe longitudinal de la vis par rapport au plan longitudinal médian de la lame du crochet permet d'écarter de l'épineuse la zone d'appui de cette lame sur l'arc postérieur. Compte tenu de 25 l'anatomie de l'arc postérieur du patient on obtient ainsi une surface d'appui convenable pour la lame du crochet sans devoir entailler l'arc postérieur, ou, le cas échéant, en l'entaillant très légèrement, ce qui constitue un avantage important par rapport à une des réalisations 30 connues rappelées ci-dessus.

Par ailleurs, le fait de prévoir une liaison élastique entre les deux vis par un organe de liaison

agissant en distraction permet avantageusement, compte tenu en outre du fait que les deux vis sont orientées dans des directions divergentes, d'appliquer sur chaque crochet, par les extrémités de cet organe de liaison comprimé, des forces axiales aux vis et dirigées vers les facettes supérieures de la vertèbre. Ces forces maintiennent fermement les lames des crochets appliquées sur l'arc postérieur.

Suivant un mode de réalisation de l'invention, l'organe de liaison élastique a une forme sensiblement en double oméga ou en M à sommets arrondis, reliés par un raccord central arrondi autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont constituées par des embouts ayant un profil complémentaire de celui de la partie correspondante de chaque vis.

Ainsi le profil de cet organe de liaison formant une lame élastique, lui permet de venir s'insérer entre les épineuses de deux vertèbres successives sans les toucher. D'autre part, ces embouts terminaux s'opposent à toute rotation des vis autour de leur axe, donc à tout recul de ces vis par rotation, grâce au profil conjugué des embouts et des zones d'appui correspondante des vis.

D'autres particularités et avantages de l'invention apparaîtront au cours de la description qui va suivre, faite en référence aux dessins annexés qui en illustrent une forme de réalisation à titre d'exemple non limitatif.

La figure 1 est une vue en perspective à échelle agrandie d'une vertèbre équipée d'une forme de réalisation de l'implant pour le traitement chirurgical d'une fracture isthmique de cette vertèbre.

La figure 2 est une vue en perspective éclatée à

échelle agrandie de l'implant de la Fig.1.

La figure 3 est une vue en perspective à échelle agrandie de l'implant des Fig.1 et 2 à l'état assemblé.

5 La figure 4 est une vue de dessus à échelle agrandie de la vis et du crochet de l'implant des Fig.1 à 3.

10 Les figures 5, 6 et 7 sont des vues en élévation latérale de trois autres modes de réalisation possible des éléments d'ancrage de l'implant dans les facettes vertébrales.

La figure 8 est une vue en perspective d'un second mode de réalisation des crochets.

15 La figure 9 est une vue en perspective d'un second mode de réalisation possible de l'organe de liaison entre les éléments d'ancrage de l'implant.

La figure 10 est une vue en perspective éclatée d'un troisième mode de réalisation possible de l'organe de liaison précité.

20 La figure 11 est une vue mi-coupe mi-élévation longitudinale d'un quatrième mode de réalisation de l'organe de liaison.

La figure 12 est une vue en perspective d'un cinquième mode de réalisation possible de l'organe de liaison entre les éléments d'ancrage de l'implant.

25 La figure 13 est une vue en perspective d'un second mode de réalisation possible des moyens de blocage de l'organe de liaison et des crochets sur les éléments d'ancrage.

30 L'implant est adapté, après une greffe osseuse d'une fracture isthmique F (Fig.1) d'une vertèbre, par exemple L5, pour le traitement chirurgical de cette fracture isthmique, sans devoir prendre appui sur des vertèbres adjacentes non endommagées. La fracture F

s'étend sur les isthmes de chaque côté de l'épineuse 4.

L'implant 1 représenté aux Fig.1 à 4 comprend :

a) une paire de vis 2 destinées à être vissées chacune dans une facette supérieure vertébrale 3 de manière à peu près symétrique de chaque côté de l'épineuse 4 et suivant des axes divergents,

b) deux crochets 5 constitués monopièce chacun d'un corps 6 et d'une lame 7, le corps 6 étant percé d'un alésage cylindrique 7 lisse de passage de la vis 2. L'axe longitudinal XX de cette dernière forme avec un plan longitudinal médian P de la lame 7 un angle A approprié pour permettre un appui convenable de la lame 7 de chaque crochet 5 sur un bord correspondant 8 de l'arc postérieur 9 de la vertèbre;

c) un organe de liaison élastique 11 entre les deux vis 2, agissant en distraction,

d) et des moyens de blocage de l'organe de liaison 11 et des crochets 5 sur les vis 2, constitués dans l'exemple représenté par des écrous 23.

Le corps 6 du crochet 5 est décalé vers l'avant par rapport à la lame 7 c'est-à-dire vers la facette 3. En d'autres termes, la lame 7 est constituée d'une branche rectiligne 7a et d'une partie incurvée 7b, la branche rectiligne reliant la partie incurvée 7b au corps 6.

L'organe de liaison 11 a une forme sensiblement en double oméga ou en M à sommets 11a arrondis reliés par un raccord central arrondi 11b définissant une ondulation avec les sommets arrondis 11a. La forme arrondie du raccord central 11b à l'opposé des sommets 11a permet à une épineuse d'une vertèbre contiguë de venir se loger à l'intérieur de la boucle définie par le sommet arrondi 11b sans toucher celui-ci. L'organe de liaison 11 peut ainsi être inséré entre deux épineuses contiguës sans les toucher.

L'organe de liaison est de préférence constitué par une lame métallique élastique dont les extrémités sont constituées par des embouts 12 ayant un profil complémentaire de celui de la partie correspondante de chaque vis 2. Par rapport au plan général du reste du ressort 11 les embouts 12 sont vrillés de façon à s'étendre, lorsque le ressort 11 est au repos, dans des plans décalés angulairement dudit plan général. Ce décalage angulaire est avantageusement réalisé dans un sens tel que, après montage du ressort 11, les embouts 12 exercent une poussée élastique sur les crochets 5. De préférence ce décalage est de 17 degrés, donc égal à un angle A qui sera défini ci-après en référence à la Fig.4.

Chaque embout 2 peut avantageusement présenter un profil polygonal 13, par exemple partiellement hexagonal, dont les méplats peuvent venir s'appliquer sur un tronçon 14 à profil polygonal conjugué du profil 13, donc par exemple hexagonal et présentant ainsi une succession de six méplats longitudinaux 15.

De ce fait les profils 13 des embouts terminaux 12 peuvent venir s'appliquer dans la position angulaire choisie sur les méplats 15 correspondants, et dans la position axiale recherchée compte tenu de la longueur du tronçon 14.

Le tronçon polygonal 14 de chaque vis 2 est prolongé d'un côté par une zone 16 à filets spongieux 17 et âme conique 18 de raccordement avec le tronçon 14. La partie filetée 17, de moindre diamètre par conséquent que la partie conique 18, se termine par un téton arrondi 19. La zone filetée 16 est destinée à pénétrer dans la facette supérieure 3 associée à l'ensemble constitué par la vis 2 et son crochet support 5 (Fig.1).

Du côté opposé à la zone filetée 16, le tronçon 14

se prolonge par une partie filetée métrique 21 sur laquelle, à partir de son extrémité, est formé au moins un méplat longitudinal 22. Dans l'exemple représenté la partie filetée 21 comporte deux méplats 22 symétriques par rapport à l'axe longitudinal de la vis, et qui interrompent donc le filet de la zone 21.

Chaque corps 6, dont la surface externe peut être partiellement cylindrique et partiellement plane sur ses côtés comme représenté, peut être enfilé d'abord sur la partie filetée 21 puis sur le tronçon lisse 14. Les écrous 23 peuvent être vissés chacun sur la partie filetée 21 correspondante. Ces écrous assurent le blocage des crochets 5 et de leur lame sur les zones choisies 8 des bords de l'arc postérieur 9, ainsi que le blocage des embouts 12 dans leur position représentée à la Fig.3, où ils coiffent partiellement les tronçons 14 respectifs et sont interposés entre les corps 6 et des rondelles 23a solidaires des écrous 23.

Les écrous de blocage 23 sont complétés par un dispositif anti-recul de ces écrous sur les tiges 2, constitué dans l'exemple illustré aux dessins par la combinaison d'une collerette cylindrique 24 lisse monopiece avec l'écrou correspondant 23, et du ou des méplats terminaux 22. En effet, l'implant étant posé sur la vertèbre L5 comme illustré aux Fig.1 et 3, après vissage des écrous 23 par le chirurgien sur les extrémités saillantes filetées 21 des tiges 2, chaque collerette 24 peut être déformée au moyen d'une pince appropriée pour venir s'écraser ou se plaquer sur le ou les méplats 22. Ainsi les collerettes écrasées 24 empêchent toute rotation ultérieure des vis 2 autour de leur axe, donc tout recul et tout arrachement de ces vis des facettes 3.

Le décalage angulaire A (Fig.4) est orienté dans

le sens qui écarte la zone d'appui des lames incurvées 7 de l'épineuse centrale 4, par rapport à la zone d'appui que ces lames auraient si le plan général P contenait l'axe XX des vis 2. A titre d'exemple numérique non limitatif, l'angle A peut être avantageusement de 17 degrés environ.

Pour procéder à la pose de l'implant qui vient d'être décrit, le chirurgien agit de la manière suivante:

a) il pratique une résection du tiers ou de la moitié inférieure de l'articulaire inférieure de la vertèbre sus-jacente à la facette supérieure 3 de la vertèbre fracturée, par exemple articulaire inférieure L₄ pour fracture isthmique de L₅.

b) il fixe chaque vis 2 sur la dite facette 3 après avoir pratiqué un trou de passage dans celle-ci au moyen d'un foret et d'un taraud, puis il enfile sur cette vis le corps 6 de chaque crochet 5 jusqu'à ce que la lame 7 de ce dernier soit en appui sur l'arc postérieur 9 à l'emplacement convenable, offrant une zone d'appui satisfaisante, compte tenu du décalage angulaire A entre l'axe XX et le plan longitudinal médian P. Cet appui peut être assuré soit sans pratiquer aucune entaille sur le bord visé 8, soit en y effectuant une très légère entaille ;

c) le chirurgien monte l'organe de liaison élastique 11 en rapprochant l'un de l'autre les embouts 12 pour mettre l'organe 11 en distraction, et coiffe les tronçons 14 par les embouts 12. Les méplats des profils 13 viennent s'appliquer sur des méplats correspondants 15 dans la position angulaire choisie, en réalisant un appui stable et solide des extrémités 12 de l'organe 11 sur les vis 2. Après sa mise en place, l'organe de liaison 11 est donc contraint en compression et exerce sur les corps 6, donc aussi sur les lames 7, des forces de distraction qui,

compte tenu de l'orientation divergente des vis 2, ont des composantes coaxiales aux vis 2 et qui tendent à maintenir fermement les lames 7 appliquées contre les bords 8 de l'arc 9, donc les deux parties fracturées l'une contre l'autre.

d) Le chirurgien visse les écrous 23 sur les parties filetées 21 afin de bloquer en place l'organe de liaison 11 et les crochets 5,

e) et enfin le chirurgien pince les collerettes 24 au moyen d'un outil approprié, afin de les écraser sur les méplats 22 et ainsi empêcher tout recul des écrous 23 par desserrage.

Outre les avantages techniques déjà mentionnés, l'invention présente les suivants :

a) Le décalage angulaire A supprime la nécessité de tailler l'arc postérieur 9.

b) Le fait que le corps 6 du crochet 5 soit décalé vers l'avant par rapport à sa lame incurvée 7, c'est-à-dire vers la facette 3, de telle sorte que sa branche 7a sensiblement rectiligne prolonge jusqu'au corps 6 la partie incurvée 7b de la lame 7, réduit l'encombrement de l'implant derrière l'arc postérieur 9 par rapport à celui des implants antérieurs décrits connus. En effet la saillie postérieure par rapport aux bords 8 de l'arc postérieur 9 est alors notablement diminuée, ainsi que la saillie sous la peau du patient.

c) Les vis 2 ne peuvent plus se dévisser et donc s'arracher des facettes 3. En effet les collerettes 24 s'opposent à toute rotation des vis 2 autour de leur axe, donc à tout recul de ces vis. De plus il a été exposé ci-dessus que les embouts 12 exercent sur les vis 2 des forces de distraction dont les composantes axiales aux vis sont dirigées vers les facettes 3 et maintiennent donc les

lames 7 fermement appliquées sur l'arc postérieur 9. Du fait que les écrous 23 ne peuvent se desserrer, les composantes axiales des forces de distraction précitées contribuent également à maintenir les vis 3 dans les trous correspondants des facettes 3, donc à s'opposer à leur recul par rotation.

5 d) Le fait de munir chaque vis 2 d'une zone 16 à filetage spongieux et à âme conique 18 permet d'assurer aux filets 17 une prise sur l'os largement supérieure à un
10 filet habituel; de plus après percement des facettes (zone corticale, os spongieux puis nouvelle zone corticale) le trou de passage de la vis 2 a été légèrement agrandi, et le cône 18, en pénétrant dans ce trou, permet de bien
15 appliquer la vis 2 contre les parois du trou et donc évite ainsi toute apparition de jeu. De ce fait la vis 2 est fermement bloquée sur l'os de la facette 3. Cette suppression de tout jeu résulte de la compression de la paroi osseuse du trou, grâce à l'âme conique 18, qui réduit la
20 profondeur des filets par rapport à celle de la zone des filets 17.

e) Par rapport aux réalisations antérieures connues, l'encombrement derrière les lames ou bords 8 de l'arc postérieur 9 est encore réduit grâce à la mise en oeuvre des collerettes 24 anti-recul. En effet celles-ci
25 sont moins encombrantes que des contre-écrous, le gain de longueur étant d'environ 1/2 écrou. Ainsi, dans la mesure où le chirurgien effectue un choix judicieux de la longueur des vis 2, les extrémités arrière de celles-ci débordent très peu par rapport aux bords postérieurs de
30 l'arc 9.

La très bonne tenue de la vis d'ancrage 2 est obtenue grâce à la forme du filetage dans l'os, le filet spongieux 17 ayant en effet la particularité de présenter

une surface d'appui maximum dans un volume minimum. La fin de filet dont le noyau 18 est conique assure une meilleure résistance de la vis à la flexion, car des efforts dans ce sens sont appliqués lors de la mise en position de l'organe de liaison élastique 11. Ces efforts sont développés par la réaction de l'effet ressort lors de la mise en compression de cette lame 11.

La liaison entre vis 2 et crochet 5 est effectuée de manière à laisser une liberté de translation et de rotation du crochet 5 sur la vis 2, permettant au crochet de se positionner dans les meilleures conditions sur l'arc postérieur. Cette liaison a aussi pour fonction, par l'intermédiaire de la lame ressort 11 ainsi que par le positionnement angulaire des deux vis 2, de créer une action du type ressort sur les crochets (effet amortisseur) permettant à ces derniers d'être toujours en action sur la greffe osseuse.

Les corps des vis 2 étant de forme hexagonale dans leur partie centrale 14, ainsi que les profils 13 de préhension de l'organe élastique 11, cet agencement autorise un mouvement de translation entre ces deux éléments et ainsi permet l'effet amortisseur précité.

Par contre, ces deux pièces 2 et 11 sont bloquées en rotation, ce qui évite le dévissage de la vis à os 2 dans son encastrement osseux.

On a représenté aux Fig.5 à 13 diverses variantes de réalisation possibles de certains éléments constitutifs de l'implant selon l'invention.

La Fig.5 montre ainsi un élément d'ancrage dans une facette vertébrale constitué par une cheville 25 complétée par une tige filetée 27.

La Fig.6 illustre une troisième possibilité dans laquelle l'élément d'ancrage est constitué par un crochet

28 prenant appui sur la facette 3 et complété par une tige filetée 29, et enfin

5 La Fig.7 montre une quatrième variante dans laquelle l'élément d'ancrage est formé par une vis 31 équipée d'un écrou 32 prenant appui derrière la facette vertébrale 3.

10 Ces modes de réalisation sont toutefois moins avantageux que les vis 2 illustrées aux Fig.1 à 4 car leur mise en place présente des difficultés. De plus le démontage d'une cheville 25 et d'un écrou 32 n'est pas possible.

15 La Fig.8 montre un crochet 33 dont la lame 34 a un profil en V ou U arrondi et dont le corps 35 est décalé vers l'extrémité libre de l'une 34a des branches 34a, 34b de la lame 34, à savoir vers l'avant c'est-à-dire vers la facette correspondante 3. Dans le corps 35 est percé un alésage 36 de passage de la tige de l'élément d'ancrage tel que 2. Le corps 35 s'étend dans le plan moyen général de la lame 34 et ne présente donc pas le décalage angulaire A décrit ci-dessus en référence à la Fig.4. Il est percé d'un trou latéral 37 pour le passage d'une vis de fixation de l'élément d'ancrage traversant l'alésage 36. Le décalage du corps 35 vers l'avant présente l'avantage de diminuer l'encombrement postérieur du crochet au niveau de l'arc vertébral. Toutefois l'absence de décalage angulaire entre le corps 35 et son alésage 36 et le plan général de la lame 34 rend ce crochet moins avantageux que le crochet 5 du premier mode de réalisation décrit.

25 La Fig.9 montre une première forme de réalisation possible de l'organe de liaison entre les éléments d'ancrage 2, 27, 29, 31. Cet organe est ici constitué par une barrette 38 dans les extrémités de laquelle sont ménagés deux trous 39, 41 dont l'un (41) est oblong. Ces trous

30

sont adaptés pour le passage des éléments d'ancrage respectifs, le trou oblong 4 permettant, avant blocage, un réglage de la position transversale de l'élément d'ancrage correspondant au moyen d'une pince de distraction. La
5 barrette 38 assure donc une liaison monobloc. Elle est relativement difficile à mettre en place et ne produit aucune action de ressort, contrairement à l'organe de liaison 11 décrit en référence aux Fig.1 à 4.

Le troisième mode de réalisation possible de
10 l'organe de liaison, représenté à la Fig.10, est constitué par la combinaison d'un ressort lame 42 sensiblement en forme de U arrondi et à extrémités 43 recourbées, et de deux ressorts spirales tels que 44. Ces derniers sont associés chacun à une extrémité 43 de telle sorte que
15 l'élément d'ancrage respectif puisse traverser l'extrémité recourbée 43 et le ressort spirale associé 44, lequel après blocage de l'ensemble est comprimé et exerce une poussée élastique sur le crochet 5 (ou 33). Cette variante de réalisation présente toutefois l'inconvénient d'être
20 relativement encombrante en direction postérieure.

La Fig.11 illustre une troisième forme de réalisation possible dans laquelle l'organe de liaison est constitué par un cylindre 45 contenant un piston 46 pouvant coulisser à l'intérieur du cylindre 45, dans
25 lequel est logé un ressort 47 qui sollicite élastiquement le piston 46 vers l'extérieur du cylindre 45. Sur les extrémités de ces derniers sont articulées des bagues respectives 48, pouvant être enfilées sur les éléments d'ancrage de l'implant et tournées d'un angle approprié,
30 de préférence de 17° comme l'angle A. La liaison produite par ce dispositif est donc élastique grâce à la compression du ressort 47. Toutefois ce dispositif est d'une réalisation relativement complexe.

La Fig.12 illustre une cinquième forme de réalisation de l'organe de liaison ici constitué par un ressort 49 sensiblement en arc de cercle, dont les extrémités sont profilées pour constituer des embouts 51 complémentaires des parties correspondantes des éléments d'ancrage. Les embouts 51 sont avantageusement décalés angulairement du plan général du reste du ressort 49 lorsque ce dernier est au repos. Ce décalage angulaire est choisi dans un sens tel que, après montage du ressort 49 sur les éléments d'ancrage, les embouts 51 exercent une poussée élastique sur les crochets. De préférence, le décalage angulaire des embouts 51 est égal à l'angle A (Fig.4).

La Fig. 13 montre une seconde forme de réalisation possible des moyens de blocage de l'organe de liaison (11, 38...) : ces moyens sont ici constitués par des rondelles 52 dont les ouvertures centrales délimitent des pattes radiales flexibles 53, séparées par des oeillets 54. Les pattes radiales 53 sont dimensionnées de façon à définir entre elles un diamètre légèrement inférieur à celui de l'élément d'ancrage tel que 27 ou 29, de façon à pouvoir être enfilées par friction sur ces éléments d'ancrage et ensuite à interdire tout retour en arrière des rondelles 52. Ces dernières doivent être réalisées en un matériau biocompatible et qui ait une élasticité suffisante pour assurer un fonctionnement fiable, tel que l'acier inoxydable.

Il convient encore d'ajouter que le fait que les embouts 12 ou 51 de l'organe de liaison élastique 11, 59 soient vrillés, de préférence de 17 degrés par rapport au plan général du reste de cet organe, assure un excellent appui de ces embouts sur l'arrière des crochets 5 et permet un coulisement aisé sur les vis 2.

L'implant selon l'invention présente l'avantage

important qu'aucun effet de traction n'est exercé sur les éléments d'ancrage tels que les vis 2.

REVENDICATIONS

1. Implant (1) pour le traitement chirurgical d'une fracture isthmique vertébrale (F), caractérisé en ce qu'il comprend :

5 - un premier sous-ensemble et un second sous-ensemble comportant chacun un élément (2) adapté pour être fixé à une partie antérieure de la vertèbre fracturée d'un côté d'une épineuse (4) de cette vertèbre, et un organe (5) adapté pour être fixé à une partie postérieure de la vertèbre, cet organe étant associé à l'élément précité, et les deux sous-ensembles étant orientés suivant des axes divergents de part et d'autre de l'épineuse,

10 - un organe (11) de liaison entre lesdits premier et second sous-ensembles, monté de manière à pouvoir rapprocher l'un de l'autre ledit élément et ledit organe de chaque sous-ensemble,

15 - et chaque sous-ensemble est pourvu de moyens de retenue (23) aptes à éviter la dissociation desdits éléments et desdits organes adaptés pour être fixés à une partie postérieure de la vertèbre.

20 2. Implant selon la revendication 1, caractérisé en ce que l'organe (11) de liaison est élastique, et agencé pour développer sur lesdits éléments (2) des forces de distraction ayant des composantes dirigées suivant les directions axiales des éléments et qui tendent à appliquer contre le bord d'un arc postérieur de la vertèbre lesdits organes (5) fixés à ladite partie postérieure de la vertèbre.

25 3. Implant selon la revendication 2, caractérisé en ce que lesdits éléments destinés à être fixés à la partie antérieure de la vertèbre sont des vis (2) adaptées pour être vissées dans les facettes vertébrales, en ce que lesdits organes (5) destinés à être fixés à une partie

postérieure de la vertèbre sont des crochets monopièce comprenant chacun un corps (6) et une lame (7), le corps étant percé d'un alésage (10) de passage de la vis associée, et l'alésage (10) du corps (6) des crochets (5) a un
5 axe longitudinal (XX) qui forme avec un plan longitudinal médian (P) de la lame (7) un angle (A) approprié pour permettre un appui convenable de la lame du crochet sur un bord (8) correspondant de l'arc postérieur (9) de la vertèbre (L5).

10 4. Implant selon la revendication 3, caractérisé en ce que chaque crochet (5) a une forme en U ou en V avec une branche (7a) plus longue que l'autre (7b) et qui porte le corps (6) au voisinage de son extrémité libre.

15 5. Implant selon la revendication 4, caractérisé en ce que l'organe de liaison élastique (11) a une forme sensiblement en double oméga ou en M à sommets arrondis (11a), reliés par un raccord central arrondi (11b) autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont
20 constituées par des embouts (12) ayant un profil (13) complémentaire de celui de la partie correspondante (14) de chaque vis (2).

25 6. Implant selon la revendication 5, caractérisé en ce que, lorsque le ressort (11) est au repos, les embouts (12) s'étendent dans des plans décalés angulairement du plan général du reste du ressort, et ce décalage angulaire est réalisé dans un sens tel que, après montage du ressort sur les éléments d'ancrage (21), les embouts exercent une poussée élastique sur les crochets (5).

30 7. Implant selon la revendication 3, caractérisé en ce que ladite partie (14) des vis (2) recevant les embouts terminaux (12) dudit organe de liaison (11) a une section polygonale et constitue un tronçon conjugué d'un

profil polygonal interne (13) de chaque embout, lequel empêche ainsi toute rotation de la vis autour de son axe (XX).

5 8. Implant selon la revendication 7, caractérisé en ce que le tronçon polygonal (14) est prolongé d'un côté par une zone (16) à filet spongieux (17) et âme conique (18) destinée à pénétrer dans la facette associée (3) de la vertèbre (L5...), et du côté opposé par une partie
10 filetée (21), et en ce que lesdits moyens de blocage de l'organe de liaison (11) comprennent des écrous (23) vissés chacun sur ladite partie filetée (21) afin de bloquer les embouts (12) de l'organe de liaison entre les corps (6) des crochets (5) et des écrous.

15 9. Implant selon la revendication 5, caractérisé en ce que lesdits moyens (23) de blocage sont complétés par un dispositif anti-recul des écrous (23) sur les tiges (2).

20 10. Implant selon la revendication 7, caractérisé en ce que le dispositif anti-recul est constitué par la combinaison d'une collerette (24) monopièce avec chaque écrou (23) et d'au moins un méplat longitudinal (22) formé sur ladite partie filetée (21) de chaque tige (2), la collerette pouvant être déformée après vissage de l'écrou afin de venir se plaquer sur le méplat.

25 11. Implant selon la revendication 3, caractérisé en ce que l'angle (A) entre l'axe longitudinal (XX) de chaque vis (2) et le plan médian (P) de la lame (7) du crochet (5) est d'environ 17 degrés.

30 12. Implant selon la revendication 2, caractérisé en ce que les éléments de fixation dans les facettes vertébrales (3) sont des chevilles (25), équipées de vis (27) ou des crochets (28), prolongés par des vis (29), ou des systèmes vis-écrous (31, 32).

13. Implant selon la revendication 2, caractérisé en ce que les éléments de fixation à ladite partie postérieure sont des crochets (33) ayant un profil en U ou en V avec un corps (35) décalé vers l'extrémité de l'une (34a) des branches (34a, 35b) du U ou du V.

14. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison est une barrette (38) dans les extrémités de laquelle sont ménagés deux trous (39, 41) dont l'un (41) est oblong, adaptés pour le passage des éléments de fixation respectifs, le trou oblong permettant un réglage de la position transversale de l'élément de fixation correspondant (2, 27, 29...).

15. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison est formé par la combinaison d'un ressort lame (42) sensiblement en U et à extrémités recourbées (43) et de deux ressorts spirales (44) associés chacun à une extrémité recourbée de telle sorte que cette dernière et le ressort spirale correspondants puissent être traversés par l'élément de fixation respectif (2...) avec production d'une poussée élastique sur le crochet (5) par le ressort spirale comprimé.

16. Implant selon la revendication 1, caractérisé en ce que l'organe de liaison comporte un cylindre (45) contenant un piston (46) sollicité élastiquement vers l'extérieur du cylindre par un ressort (47) logé dans ce dernier, des bagues (48) étant articulées aux extrémités du cylindre et du piston.

17. Implant selon la revendication 3, caractérisé en ce que l'organe de liaison est un ressort (49) sensiblement en arc de cercle dont les extrémités (51) sont profilées pour être complémentaires des parties correspondantes desdits éléments de fixation (2...), et forment des embouts situés, lorsque le ressort est au repos, dans des

plans décalés angulairement du plan général du reste du ressort, ce décalage angulaire étant choisi dans un sens tel que, après montage du ressort sur les éléments d'ancrage, les embouts exercent une poussée élastique sur les crochets (5).

18. Implant selon la revendication 3, caractérisé en ce que lesdits moyens de butée de l'organe de liaison (11,...) et des crochets (5) sur les éléments de fixation (2) sont des rondelles (52) dont les ouvertures centrales délimitent des pattes radiales flexibles (53) de friction et de retenue des rondelles sur lesdits éléments de fixation.

19. Procédé de pose d'un implant (1) selon l'une des revendications 3 à 17, selon lequel :

a) on pratique une résection du tiers ou de la moitié inférieure de l'articulaire inférieure de la vertèbre sus-jacente à la facette supérieure (3) de la vertèbre fracturée (L5),

b) on fixe l'élément de fixation (2) sur ladite facette, on enfile sur cet élément le corps (6) du crochet (5) jusqu'à ce que la lame (7) de ce dernier soit en appui sur l'arc postérieur (9) de la vertèbre,

c) on monte l'organe (11) de liaison sur les éléments d'ancrage,

d) on met en place les moyens de butée (23...) sur les éléments de fixation.

20. Procédé selon la revendication 18, dans lequel l'organe de liaison (11) est élastique et a une forme sensiblement en double oméga ou en M à sommets arrondis (11a) reliés par un raccord central arrondi (11b) autorisant le logement de l'épineuse d'une vertèbre supérieure adjacente, et les extrémités de cet organe de liaison sont constituées par des embouts (12) ayant un profil (13)

complémentaire de celui de la partie correspondante (14) de chaque vis (2) constituant les éléments de fixation précités, et les moyens de butée comprennent des écrous (23) prolongés par des collerettes (24), procédé selon lequel :

5 a) on fixe la vis (2) sur ladite facette, on enfile sur cette vis le corps (6) du crochet (5) jusqu'à ce que la lame (7) de ce dernier soit en appui sur l'arc postérieur (9) de la vertèbre,

10 b) on monte l'organe (11) de liaison élastique en compression sur les vis en coiffant les parties correspondantes (14) des vis (2) par les embouts (12) dudit organe,

c) on visse les écrous (23) sur les parties filetées (21) des vis (2) afin de bloquer en place, 15 l'organe de liaison et les crochets,

d) et on pince les collerettes (24) des écrous afin de les écraser sur les méplats (22) des vis afin d'empêcher tout recul des écrous par desserrage.

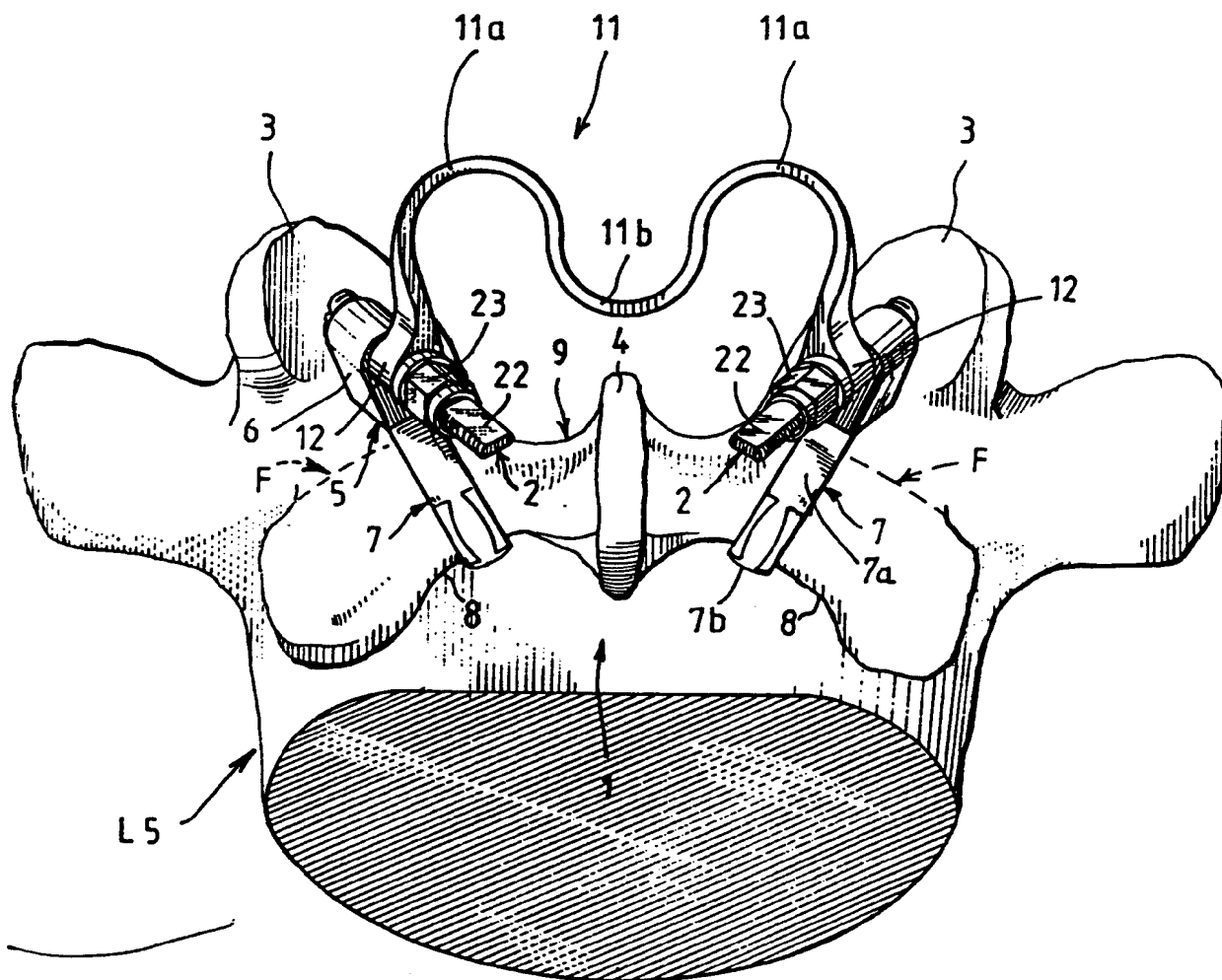


FIG.1

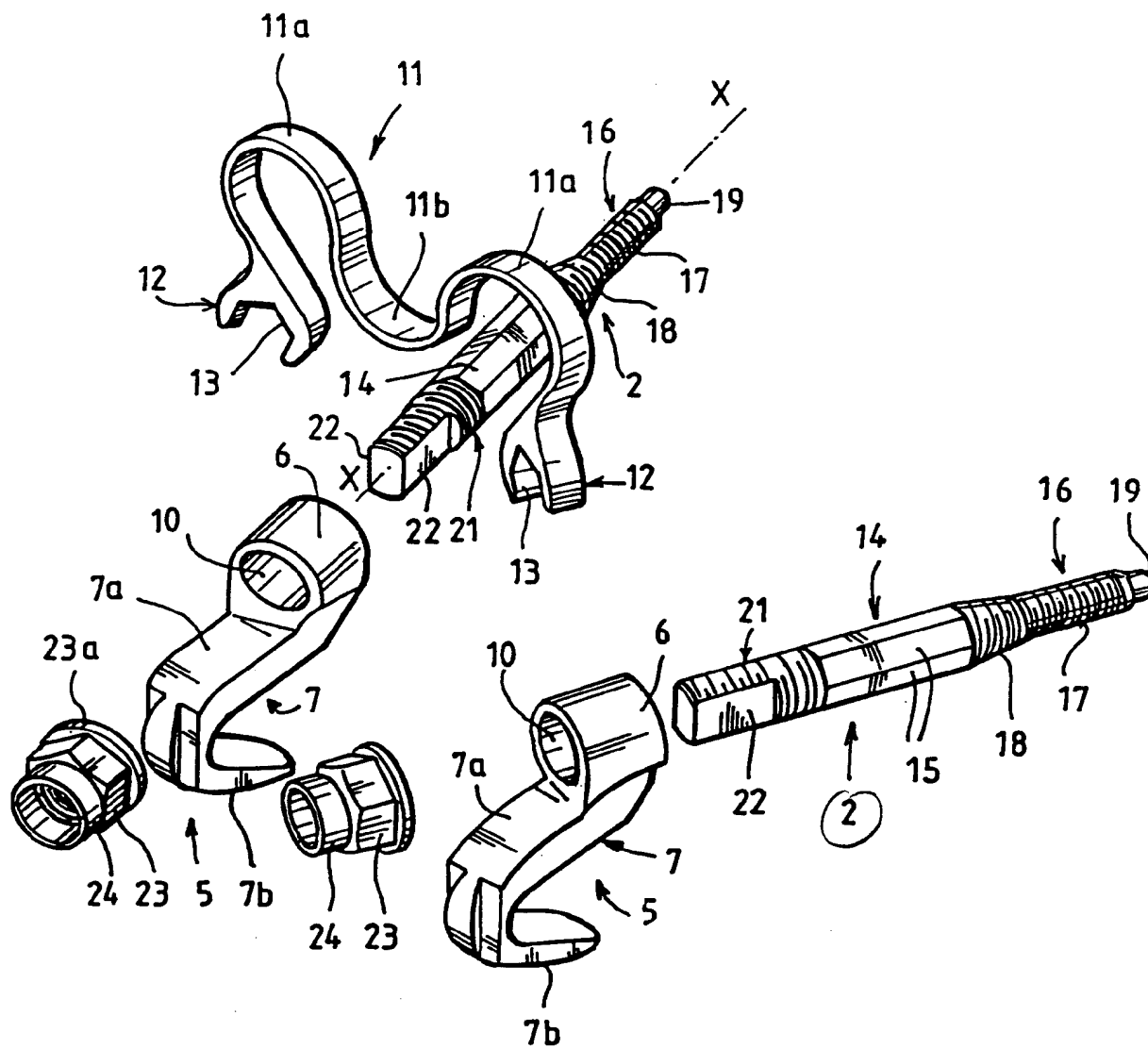


FIG. 2

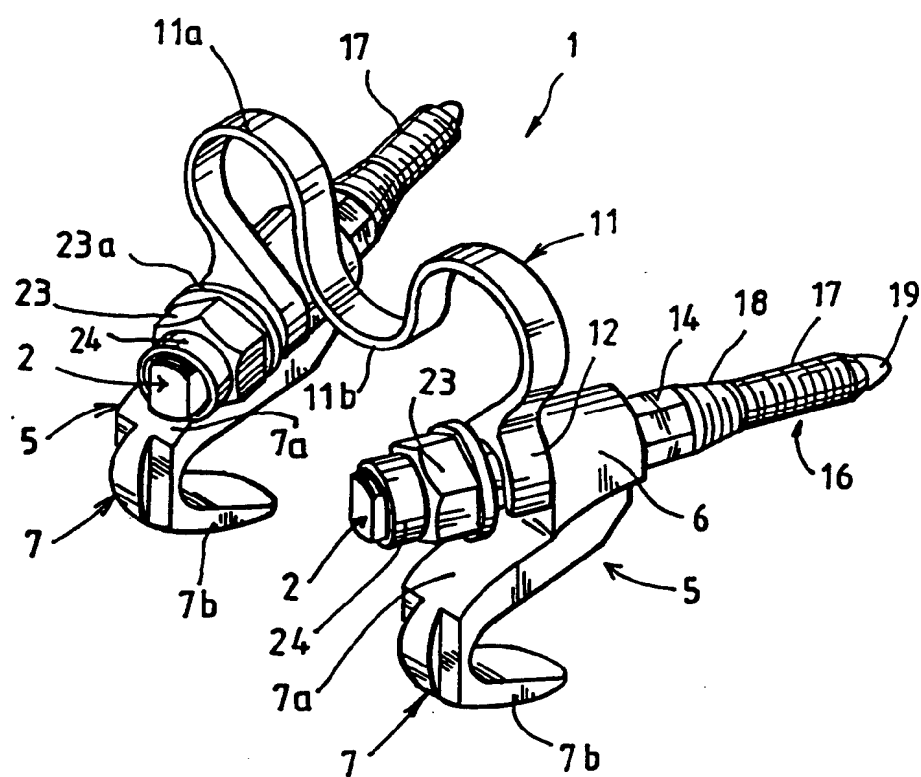


FIG.3

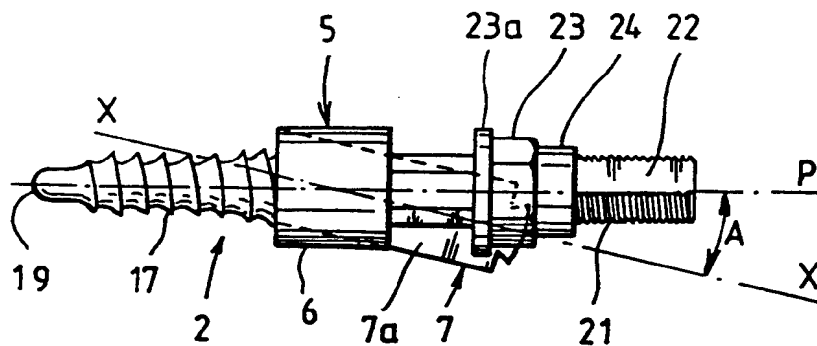


FIG. 4

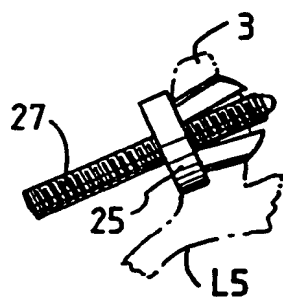


FIG. 5

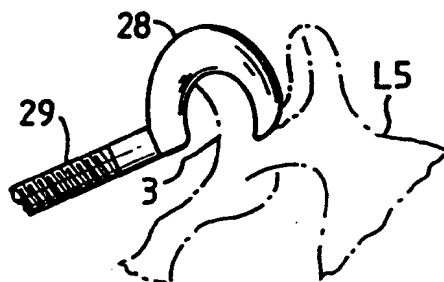


FIG. 6

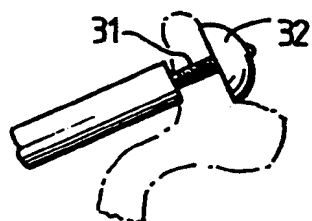
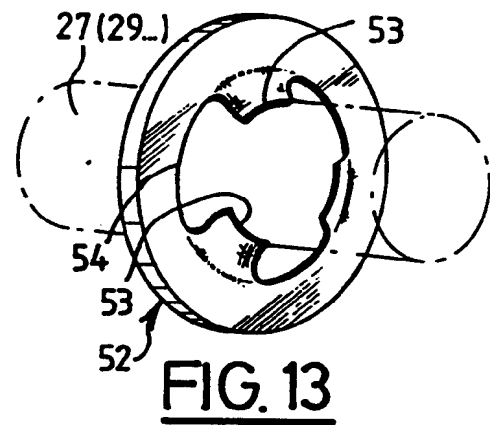
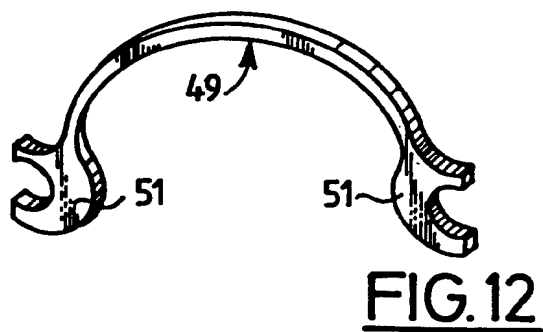
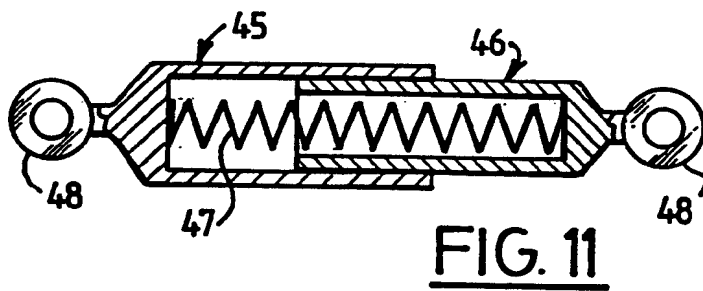
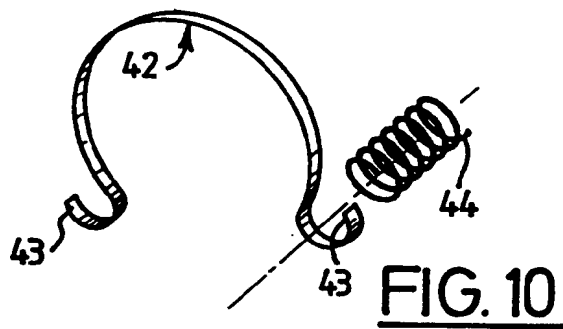
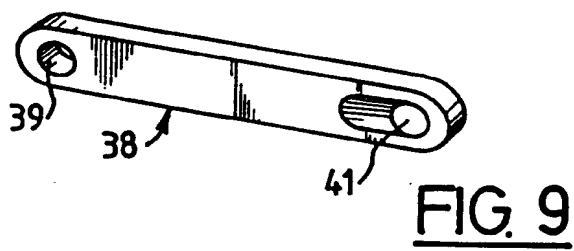
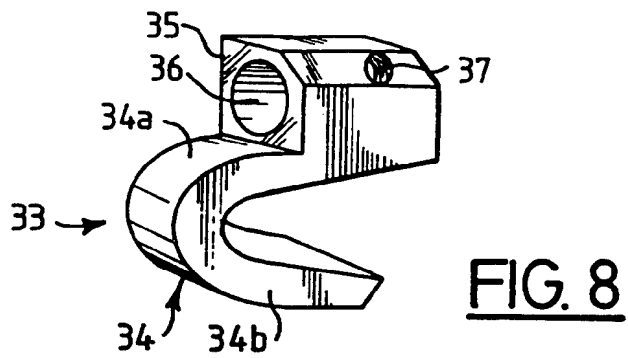


FIG. 7



INTERNATIONAL SEARCH REPORT

Internati Application No.
PCT/FR 96/00839

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 352 225 (YUAN ET AL.) 4 October 1994 see column 2, line 63 - column 3, line 55; figures 1A-2C ---	1
A	EP,A,0 283 373 (SOFAMOR) 21 September 1988 see page 5, column 6-19; figure 10 ---	1
A	DE,U,88 16 233 (DWORRAK ET AL.) 6 July 1989 see page 7, line 1-31; figures ---	1
A	WO,A,94 20048 (RAY) 15 September 1994 see abstract; figures ---	1
A	FR,A,2 697 428 (ALBY) 6 May 1994 see the whole document -----	1

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US-A-5352225	04-10-94	NONE	
EP-A-0283373	21-09-88	FR-A- 2612071	16-09-88
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		AU-B- 1280088	15-09-88
		JP-A- 1076847	22-03-89
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		JP-T- 8507458	13-08-96
		US-A- 5531745	02-07-96
		US-A- 5531747	02-07-96
		ZA-A- 9404061	16-02-95
FR-A-2697428	06-05-94	NONE	

RAPPORT DE RECHERCHE INTERNATIONALE

 Demande internationale No
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 A. CLASSEMENT DE L'OBJET DE LA DEMANDE
 CIB 6 A61B17/70

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 Documentation minimale consultée (système de classification suivi des symboles de classement)
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C. DOCUMENTS CONSIDERES COMME PERTINENTS

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A	US,A,5 352 225 (YUAN ET AL.) 4 Octobre 1994 voir colonne 2, ligne 63 - colonne 3, ligne 55; figures 1A-2C ---	1
A	EP,A,0 283 373 (SOFAMOR) 21 Septembre 1988 voir page 5, colonne 6-19; figure 10 ---	1
A	DE,U,88 16 233 (DWORRAK ET AL.) 6 Juillet 1989 voir page 7, ligne 1-31; figures ---	1
A	WO,A,94 20048 (RAY) 15 Septembre 1994 voir abrégé; figures ---	1
A	FR,A,2 697 428 (ALBY) 6 Mai 1994 voir le document en entier -----	1

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9 Septembre 1996

Date d'expédition du présent rapport de recherche internationale

13. 09. 96

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Renseignements relatifs aux membres de familles de brevets

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Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US-A-5352225	04-10-94	AUCUN	
EP-A-0283373	21-09-88	FR-A- 2612071	16-09-88
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FR-A-2697428	06-05-94	AUCUN	

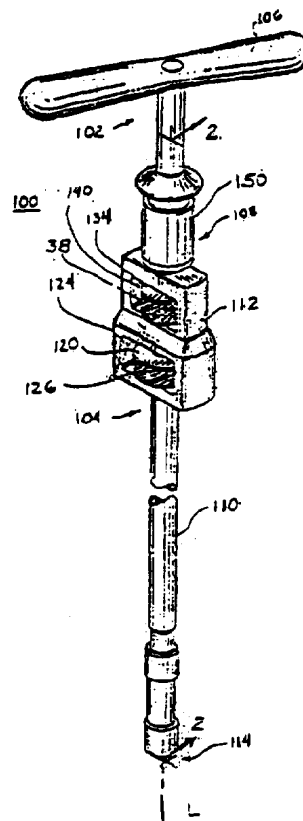
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/56		A1	(11) International Publication Number: WO 97/33525 (43) International Publication Date: 18 September 1997 (18.09.97)
(21) International Application Number: PCT/US97/03869 (22) International Filing Date: 13 March 1997 (13.03.97) (30) Priority Data: 08/616,120 14 March 1996 (14.03.96) US (71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US). (72) Inventors: WINSLOW, Charles, J.; 27 Hilton Court, Walnut Creek, CA 94520 (US). MITCHELL, Steven, T.; 776 Duke Circle, Pleasant Hill, CA 94523 (US). (74) Agent: GERSHON, Neil, D.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).			(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: APPARATUS AND METHOD FOR IMPLANT INSERTION**(57) Abstract**

Apparatus for, and methods of, inserting implants (200) are disclosed wherein the apparatus includes a handle portion (112) and a body portion attached to the handle portion (112). The body portion includes an outer tubular member (110), an inner tubular member (118) and an inner shaft (132). The outer tubular member (11) is fixed to the handle portion (112) for rotation therewith and with implant engaging structure (116) on its distal end. The inner tubular member (118) is disposed within the outer tubular member (110) and can move longitudinally and rotationally therein. Second implant engaging structure (130) is positioned at the distal end of the inner tubular member (118). The inner shaft (132) rotates relative the inner and outer tubular members and has a third implant engaging structure (144). At least one of the engaging structures attaches to a removable cap (206) of the implant.



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APPARATUS AND METHOD FOR IMPLANT INSERTION

5

BACKGROUND

This application is a continuation-in-part of U.S. application Serial No. 08/354,364, filed on December 12, 1994, which is a continuation-in-part of U.S. application Serial No. 08/306,879, filed on September 15, 1994. The contents of these applications are incorporated herein by reference.

10

1. Technical Field

This disclosure relates generally to apparatus and methods for implant insertion. More particularly, to apparatus and methods for insertion of implants to facilitate fusion of adjacent bony structure.

15

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,40,805 to Warren; 5,358,511 to Gattorna et al.; and 4,877,020 to Vich.

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Some implants are particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Implants in the form of fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments are disclosed, for example, in U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.;

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5,015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed in commonly assigned U.S. Patent No. 5,026,373, incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily done using an anterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the discal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

When installing these specialized implants, an insertion tool is used to position the implant in the desired intervertebral location. See, for example, U.S. Patent Nos.: 3,848,601 to Ma et al.; 4,501,269 to Bagby; 4,877,020 to Vich; and 4,878,915 to Brantigan. Once in position, the insertion tool is removed and, where the implant structure permits, bone chips or other bone growth inducing substances are packed into the implant in vivo. Subsequently, an end cap or other sealing structure is positioned to close the implant. See, for example, commonly assigned U.S. Patent No. 4,961,740 to Ray et al. incorporated herein by reference.

Typical insertion tools use either a single implant engagement structure or, at most, two implant engagement structures to facilitate positioning of the implant. For example, in U.S. Patent No. 4,501,269 to Bagby, prongs are used to engage the implant. In U.S. Patent Nos. 4,878,915 to Brantigan and 5,015,247 to Michaelson, a threaded rod and slot are used to engage the implant. In U.S. Patent Nos.: 4,961,740 to Ray et al.;

5,489,308 and 5,489,307, both to Kuslich et al.; and 4,936,838 to Bagby, a single central shaft is used. In all of these insertion tools, no structure is provided to permit the insertion tool to attach to an outer peripheral portion of the implant, either in vitro or in vivo.

Further, these tools do not provide structure which separately engages both the implant and the implant closure, e.g. an end cap.

Accordingly, a need exists for an insertion tool which is capable of either inserting an implant preloaded with bone chips, etc. Such in vitro packing facilitates the surgical procedure because it is often time consuming and relatively difficult, especially for example in cervical applications, to pack the cage in vivo. It would also be advantageous if such insertion tool could be additionally used to insert/position an empty implant for subsequent in vivo packing and closure.

SUMMARY

Apparatus for and methods of inserting implants are disclosed wherein the apparatus includes a handle portion and a body portion attached to the handle portion and defining a longitudinal axis. The body portion includes an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis. The outer tubular member has first implant engaging structure adjacent a distal end. An inner tubular member is disposed at least partially within the outer tubular member and is mounted for longitudinal motion relative to the outer tubular member. Second implant engaging structure is positioned adjacent a distal end of the inner tubular member. The body portion further includes an inner shaft, coaxially mounted at least partially within the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

In a method for inserting an implant having a hollow portion with a closed distal end and a removable cap, the first, second and third implant engaging structures are attached to the implant with at least one of the engaging structures attached to the removable cap and another of the engaging structure attached to the hollow portion. The implant is

preferably preloaded with bone chips and/or bone growth inducing substances prior to attachment. Thereafter, the preloaded implant is inserted into the desired surgical location.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Various embodiments of the subject implant insertion apparatus are described below with reference to the drawings wherein:

FIG. 1 is a perspective view of an implant insertion apparatus constructed in accordance with a preferred embodiment of the subject disclosure;

10 FIG. 2 is a side view in cross-section of the implant insertion apparatus taken along line 2-2 of FIG. 1;

FIG. 2A is an enlarged side view in cross-section of the connection between the handle portion and the body portion of the implant insertion apparatus of FIG. 1;

FIG. 2B is an enlarged perspective view of the distal ends of the outer and inner tubular members of the implant insertion apparatus of FIG. 1;

15 FIG. 2C is an enlarged perspective view of an interchangeable distal end of the outer tubular member of the implant insertion apparatus of FIG. 1;

FIG. 3 is an enlarged perspective view of one type of implant configured for interbody fusion;

20 FIG. 4 is an enlarged proximal end view of the implant of FIG. 3 illustrating the structure of the removable end cap;

FIG. 5 is an enlarged end view in cross-section of the implant taken along line 5-5 of FIG. 3.

FIG. 6 is an enlarged perspective view of the implant of FIG. 3 with parts separated and loading of bone chips in process;

25 FIG. 6A is a side view in partial cross-section showing an end cap mounted to the inner tubular member and the inner shaft;

FIG. 7 is a perspective view of a preloaded implant with removable end cap in place;

FIG. 8A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 and the implant of FIG. 7;

FIG. 8B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner tubular member as shown in FIG. 8A;

FIG. 9A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 with the second and third implant engagement structure attached to the removable cap of the implant of FIG. 7;

FIG. 9B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner tubular member and the inner shaft as shown in FIG. 9A;

FIG. 10A is an enlarged side view in partial cross-section illustrating the distal end of the implant insertion apparatus of FIG. 1 with the first, second and third implant engagement structure attached to the implant of FIG. 7;

FIG. 10B is an enlarged side view of the housing and rotation wheels of the body portion illustrating the relative position of the inner shaft, the inner tubular member and the outer tubular member as shown in FIG. 10A;

FIG. 11 is a side view illustrating the insertion of the implant of FIG. 7 using the insertion apparatus of FIG. 1; and

FIG. 12 is an enlarged top view in partial cross-section of a pair of implants in place in the intervertebral space of a lumbar spinal section.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The preferred embodiments of the apparatus and methods disclosed herein are discussed in terms of orthopedic spinal fusion procedures and apparatus. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present apparatus finds application in both open and minimally invasive procedures

including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

In the description which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now in detail to the drawings in which like reference numerals identify similar or identical elements, a preferred embodiment of the implant insertion apparatus is illustrated in FIGS. 1 and 2 and is designated generally by reference numeral 100. Implant insertion apparatus 100 includes a removable handle portion 102 and a body portion 104. Handle portion 102 has a T-handle 106 positioned at a proximal end and releasable engagement structure 108 at a distal end thereof.

Body portion 104 defines a longitudinal axis "L" and includes an outer tubular member 110 fixed to a housing 112 for longitudinal rotation therewith. First implant engaging structure 114 is positioned adjacent a distal end of outer tubular member 110. Outer tubular member 110 preferably includes a removable distal end portion 158 described below. In the embodiment shown, the implant engaging structure is a pair of distally extending tabs 116 projecting from the distal end of outer tubular member 110.

Body portion 104 further includes an inner tubular member 118 disposed at least partially within outer tubular member 110. Inner tubular member 118 is mounted for limited longitudinal motion relative to outer tubular member 110 and is independently rotatable relative to outer tubular member 110 by wheel 120. In the illustrated embodiment, set screw 122 anchors wheel 120 to the inner tubular member 118. A first cavity 124 is defined in housing 112 and is dimensioned to limit the relative longitudinal motion of inner tubular member 118 by confining wheel 120 between walls 112a, 112b. As shown in FIG. 1, the periphery of wheel 120 may be provided with knurling 126 to enhance its frictional characteristics.

Inner tubular member 118 is normally biased to a distalmost longitudinal position relative to outer tubular member 110 as shown in FIG. 2. Coil spring 127, mounted in housing 112, abuts a proximal end of inner tubular member 118 and biases

inner tubular member distally. Second implant engaging structure 128 is formed adjacent a distal end of the inner tubular member 118. In the illustrated embodiment, the second implant engaging structure 128 is a hollow polygonal structure having a plurality of flat sides 130 extending from the distal end of inner tubular member 118.

5 Body portion 104 also includes an inner shaft 132, coaxially mounted at least partially within the inner tubular member 118. Inner shaft 132 is longitudinally rotatable relative to inner tubular member 118 and outer tubular member 110 by wheel 134. As shown, set screw 136 connects wheel 134 to a distal end of inner shaft 132. In a preferred embodiment, the outer periphery of wheel 134 is provided with a friction
10 enhancing surface such as knurling 138.

 A second cavity 140 is defined in housing 112 proximal to first cavity 124 and serves to confine wheel 134, and thus inner shaft 132, to limited longitudinal motion relative to outer and inner tubular members 110 and 118, respectively between walls 112c, 112d. Wheels 120 and 134 preferably extend radially beyond at least one outer peripheral
15 surface of house 112 to facilitate actuation by the fingers of a user.

 Inner shaft 132 has third implant engaging structure 142 positioned adjacent a distal end (See Figs 2 and 6A). In the illustrated embodiment, this structure is threads 144 formed on a distal end of inner shaft 132.

 Referring now to FIGS. 2 and 2A, releasable engagement structure 108 of
20 the illustrated embodiment of implant insertion apparatus 100 includes a distal sleeve 146 having an inner surface configured to engage hexagonal projection 148 formed on a proximal end of housing 112.

 Proximal sleeve 150 is operatively associated with distal sleeve 146 and includes an internal spring loaded ball system 152 configured to releasably engage an
25 annular channel 154 which extends proximally from hexagonal projection 148. Proximal sleeve 150 is mounted on a distal end of handle portion 102 for relative longitudinal motion between a locked position (FIG. 2) and an unlocked position (FIG. 2A). In the locked position, ball system 152 is forced radially inward into annular channel 154. Spring 156 normally biases proximal sleeve 150 into this locked position. As shown in FIG. 2A, in

the unlocked position, proximal sleeve 150 is retracted to release ball system 152 from annular channel 154. This enables the removal of handle portion 102 from the body portion 104 so the handle portion can be attached to and used with other instrumentation necessary for performing the surgical procedure.

5 Referring to FIGS. 2B and 2C in view of FIG. 1, a versatile feature of the illustrated embodiment is shown. In this preferred embodiment, a distal end portion 158 of outer tubular member 110, which contains first implant engagement structure 114, is interchangeably attached via a friction fit. This allows the user to position another distal end portion 160, such as that shown in Fig. 2C, mounting either a different size (e.g.
10 diameter) implant or configuration of implant engagement structure on the same implant insertion apparatus. Thus, the insertion apparatus can be readily adapted to insert different implants.

An implant designed for use in spinal fusion procedures is shown in FIGS. 3-5 and designated generally by the reference number 200. This implant is commonly
15 referred to as a "fusion cage" and, in this embodiment, is specifically configured for a posterior access spinal fusion procedure. Subsequent discussion regarding an exemplary use of the implant insertion tool 100 will be focused on this posterior spinal fusion procedure inserting fusion cage 200. It is contemplated, however, that the disclosed implant insertion tool has broad application in a wide variety of implant insertion
20 procedures beyond either anterior or posterior spinal fusion.

Fusion cage 200 includes a body portion 202 with a closed distal end 204 and a proximal end 206. The distal end 204 is rounded or bull nosed to facilitate insertion of the fusion cage 200 relative to one or more bone structures. The proximal end 206 defines an opening 208 (FIG. 6) which communicates with an internal cavity 210 (FIG. 5)
25 defined by fusion cage 200. In the illustrated embodiment, opening 208 is threaded to receive an end cap 212. This end cap 212 is used to close off the proximal end 206 and to retain bone growth inducing substances, such as bone chips 214 (FIG. 6), packed therein.

Referring to FIG. 4, end cap 212 defines a threaded bore 216 which is configured to receive third implant engaging structure 142 of inner shaft 132 as will be

discussed in further detail below. End cap 212 also defines a substantially square depression 218 coaxial with thread bore 216 and configured to receive second implant engaging structure 128 on inner tubular member 118.

5 The proximal end 206 further defines first and second peripheral indentations 220, 222 which are centered about transverse axis "T". These peripheral indentations 220, 222 are configured to receive first implant engagement structure 114, in this case tabs 116. These indentations may also be used to line up the fusion cage 200 for proper insertion and placement between the adjacent vertebral structure.

10 A helical thread 224 is formed on the outer peripheral surface of the fusion cage 200. A plurality of apertures 226 are defined by and extend through the fusion cage 200. In the illustrated fusion cage 200, apertures 226 are formed by broaching grooves 228 (FIG. 5) in the internal surface 230 of internal cavity 210. This technique removes material from the valleys between the turns of the thread 224, thus defining apertures 226 to advantageously provide immediate contact between the vertebral body and the bone chips
15 located inside the cage when the cage is positioned in the body.

Referring now to FIGS. 6, 6A and 7, two methods of closing the end cap 212 in the opening 208 of proximal end 206 are illustrated. In FIG. 6, bone chips 214 are deposited into internal cavity 210 using forceps. Thereafter, end cap 212 can be manually threaded into opening 208 either by hand or with a socket wrench-type instrument.
20 Alternatively, end cap 212 can be positioned into engagement with second and third implant engaging structure 128, 142 of implant insertion apparatus 100. This is done by positioning the flat sides 130 of second implant engaging structure 128 into square depression 218 of end cap 212. The distal end of inner shaft 132 is then threaded into bore 216 of end cap 212 by rotating wheel 134 (FIG. 1). End cap 212 is then securely engaged
25 by the second and third implant engaging structure 128, 142. The implant insertion apparatus 100 is positioned with the engaged end cap 212 in juxtaposed axial alignment with opening 208 in proximal end 206 of fusion cage 200. Rotation of wheel 120 threads the end cap 212 into the fusion cage 200. As shown, in both methods, packing of the cage occurs outside the body. This facilitates insertion of bone chips since the chips are

individually placed with a forceps and lightly tapped, e.g., compacted, inside the cage. This is especially advantageous where access to the cage once implanted is limited and/or with smaller cages such as in cervical applications.

5 Mounting a packed fusion cage (FIG. 7) onto the insertion apparatus 100 and subsequent insertion into an intervertebral space will now be described with reference to FIGS. 8 through 12. In FIGS. 8A and 8B, the packed fusion cage is positioned in axial alignment with the proximal end of fusion cage 200, aligning tabs 116 with indentations 220, 222; flat sides 130 with square depression 218; and threads 144 with threaded bore 216.

10 Referring now to FIGS. 9A, 9B, 10A and 10B, fusion cage 200 is moved initially into engagement with inner tubular member 118 such that flat sides 130 are disposed in square depression 218 of end cap 212. Further proximal motion (indicated by the arrows in FIGS. 9A and 9B) of inner shaft 118 relative to inner shaft 132 by either pressing cage 200 against the apparatus or moving wheel 120 proximally brings threads 15 144 into engagement with threaded bore 216 and tabs 116 of outer tubular member 110 into simultaneous engagement with indentations 220 and 222. (FIG. 10A) Wheel 120 can be slightly rotated to ensure alignment of tabs 116 and indentations 220, 222. Then, wheel 134 is rotated to cause the threaded inner shaft to engage the fusion cage 200 by end cap 212 thus securely mounting the fusion cage 200 on the distal end of the implant insertion apparatus 100 as the cage 200 is pulled proximally via the engagement of the threads. 20

Thereafter, the implant insertion apparatus 100 is positioned adjacent the implant site (FIG. 11) which typically includes a pretapped bore formed in an intervertebral space between two adjacent vertebra. (Alternately, the fusion cage could be self-tapping.) The implant insertion apparatus 100 may be guided into position using a cannula or C- 25 retractor 300 to facilitate accurate insertion of fusion cage 200. The T-handle 106 is then rotated to rotate outer tubular member 110 to engage threads 224 of the fusion cage 200 (shown in phantom) in the intervertebral space 302.

Once the fusion cage 200 is in position, wheel 134 is rotated to disengage threads 144 from threaded bore 216. This releases the implant insertion apparatus 100 from the implanted fusion cage 200. (FIG. 12)

5 Note that since the fusion cage 200 is grasped and inserted by the apparatus 100 from its open end, once positioned inside the body, the end cap 212 can be removed if the user desires to view or access the bone chips in the internal cavity 210.

The implant insertion apparatus 100 can also be utilized to insert an empty implant such as fusion cage 200 into the intervertebra space and subsequently seal the fusion cage after packing the fusion cage with bone growth inducing substance in vivo. In
10 this procedure, the empty fusion cage is engaged with the first, second and third implant engagement structure 114, 128, 142 and inserted in the same manner outlined above. Once in place in the body, wheel 120 is rotated to remove end cap 212 from body portion 202 and the implant insertion apparatus with attached end cap 212 (FIG. 6A) is removed from the site.

15 Thereafter, the fusion cage 200 can be packed and the procedure reversed to thread the end cap 212 securely back into place on the body portion 202 using apparatus 100 as described above without affecting the relative position of the body portion 202 at the site. This would avoid the necessity for a separate cap insertion tool since apparatus 100 could serve the dual function of inserting the cage and attaching the end cap.

20 It will be understood that a wide variety of modifications may be made to the embodiments of the apparatus and methods disclosed herein. For example, the first, second and/or third implant engaging structures can be modified to facilitate engagement with a vast number of implants, both prosthetic and natural. Also, endoscopic, arthroscopic and percutaneous methods of use are easily accommodated. Therefore, the
25 above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. Apparatus for implant insertion comprising:
a handle portion; and
a body portion attached to the handle portion and defining a
5 longitudinal axis, the body portion including an outer tubular member fixed relative to the
handle portion for rotation therewith about the longitudinal axis, the outer tubular member
having first implant engaging structure adjacent a distal end, an inner tubular member
disposed at least partially within the outer tubular member and mounted for longitudinal
10 motion relative to the outer tubular member, the inner tubular member being rotatable
independent of the outer tubular member and having second implant engaging structure
adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner
tubular member for independent rotation relative to the inner and outer tubular members, the
inner shaft having third implant engaging structure adjacent a distal end.
- 15 2. Apparatus as in claim 1 wherein the handle portion is releasably
attached to the body portion.
3. Apparatus as in claim 1 further comprising a wheel positioned on the
inner tubular member for independent rotation thereof relative to the outer tubular member.
20
4. Apparatus as in claim 1 further comprising a wheel positioned on the
inner shaft for independent rotation thereof relative to the outer and inner tubular members.
5. Apparatus as in claim 1 wherein the first implant engaging structure
25 comprises a pair of tabs projecting from the distal end of the outer tubular member.
6. Apparatus as in claim 1 wherein the second implant engaging
structure comprises a polygonal structure extending from the distal end of the inner tubular
member.

7. Apparatus as in claim 1 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

5 8. Apparatus as in claim 1 wherein the first implant engaging structure is removably mounted to the body portion.

9. Apparatus as in claim 2 wherein the handle portion is T-shaped.

10 10. Apparatus for implant insertion comprising:
a handle portion; and
a body portion defining a longitudinal axis and having a proximal end configured to engage the handle portion, a distal end configured to engage an implant, and a housing fixed relative to the proximal end and positioned intermediate the proximal and distal ends, the body portion including an outer tubular member fixed to the housing and extending distally therefrom, the outer tubular member having first implant engaging structure at a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member, the inner tubular member including a first wheel confined at least partially within a first cavity in the housing for rotating the inner tubular member relative to the outer tubular member, the inner tubular member having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner tubular member, the inner shaft including a second wheel confined at least partially within a second cavity in the housing for independently rotating the inner shaft relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

11. Apparatus as in claim 10 wherein the first implant engaging structure comprises a pair of tabs projecting from the distal end of the outer tubular member.

12. Apparatus as in claim 10 wherein the second implant engaging structure comprises a polygonal structure extending from the distal end of the inner tubular member.

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13. Apparatus as in claim 10 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

14. Apparatus as in claim 10 wherein the first implant engaging structure is removably mounted to the body portion.

10

15. Apparatus as in claim 10 wherein the handle portion is T-shaped.

15

16. Apparatus as in claim 11 wherein the tabs are on radially opposed sides of the longitudinal axis and are configured to engage an outer peripheral wall of an implant.

17. In an apparatus for insertion of a hollow implant having a closed distal end section accessible through a removable proximal end cap, the apparatus having a handle portion and a body portion with implant engaging structure adjacent a distal end thereof, the improvement comprising a body portion attached to the handle portion and defining a longitudinal axis, the body portion including an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis, the outer tubular member having first implant engaging structure adjacent a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular member, the inner tubular member being rotatable independent of the outer tubular member and having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within

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the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end.

5 18. Apparatus as in claim 17 wherein the handle portion is releasably attached to the body portion.

10 19. Apparatus as in claim 17 further comprising a wheel positioned on the inner tubular member for independent rotation thereof relative to the outer tubular member.

 20. Apparatus as in claim 17 further comprising a wheel positioned on the inner shaft for independent rotation thereof relative to the outer and inner tubular members.

15 21. Apparatus as in claim 17 wherein the first implant engaging structure comprises a pair of tabs projecting from the distal end of the outer tubular member.

20 22. Apparatus as in claim 21 wherein the pair of tabs are positioned on the distal end of the outer tubular member to engage the closed distal end section of the prosthetic implant.

 23. Apparatus as in claim 17 wherein the second implant engaging structure comprises a polygonal structure extending from the distal end of the inner tubular member.

25 24. Apparatus as in claim 23 wherein the polygonal structure is positioned on the distal end of the inner tubular member to engage the proximal end cap of the prosthetic implant.

25. Apparatus as in claim 17 wherein the third implant engaging structure comprises a threaded portion formed on the distal end of the inner shaft.

5 26. Apparatus as in claim 25 wherein the threaded portion formed on the distal end of the inner shaft is configured to threadably engage the proximal end cap of the prosthetic implant.

27. A method of inserting an implant comprising the steps of:
providing an apparatus including a handle portion and a body
10 portion attached to the handle portion and defining a longitudinal axis, the body portion including an outer tubular member fixed relative to the handle portion for rotation therewith about the longitudinal axis, the outer tubular member having first implant engaging structure adjacent a distal end, an inner tubular member disposed at least partially within the outer tubular member and mounted for longitudinal motion relative to the outer tubular
15 member and having second implant engaging structure adjacent a distal end and an inner shaft, coaxially mounted at least partially within the inner tubular member for independent rotation relative to the inner and outer tubular members, the inner shaft having third implant engaging structure adjacent a distal end;
providing an implant having a hollow portion with a closed distal
20 end and a removable proximal end cap;
attaching the first, second and third implant engaging structures to the implant; and
inserting the implant into a desired surgical location.

25 28. A method as in claim 27 wherein the implant includes a threaded portion formed on an outer peripheral surface of the hollow closed distal end and the inserting step including rotating the implant into a desired surgical location.

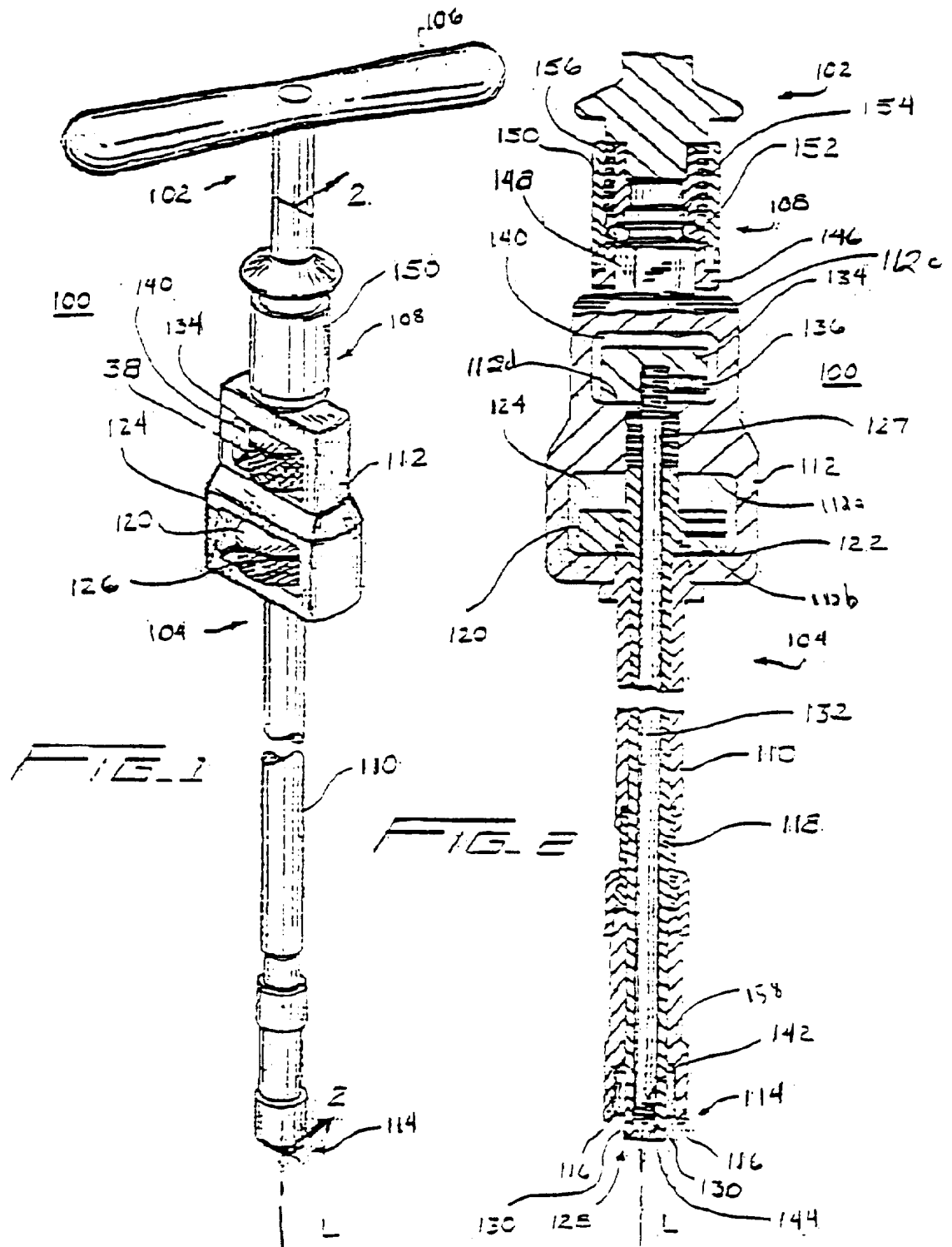
29. A method as in claim 28 wherein the first implant engaging structure includes a pair of tabs positioned on a distal end of the outer tubular member and the attaching step includes engaging the tabs with the hollow closed distal end of the implant.

5 30. A method as in claim 28 wherein the attaching step includes engaging the second and third implant engaging structure to the proximal end cap of the implant.

10 31. A method as in claim 27 further comprising the step of loading the implant with bone growth stimulation media.

 32. A method as in claim 31 wherein the step of loading the implant is carried out before the implant is inserted.

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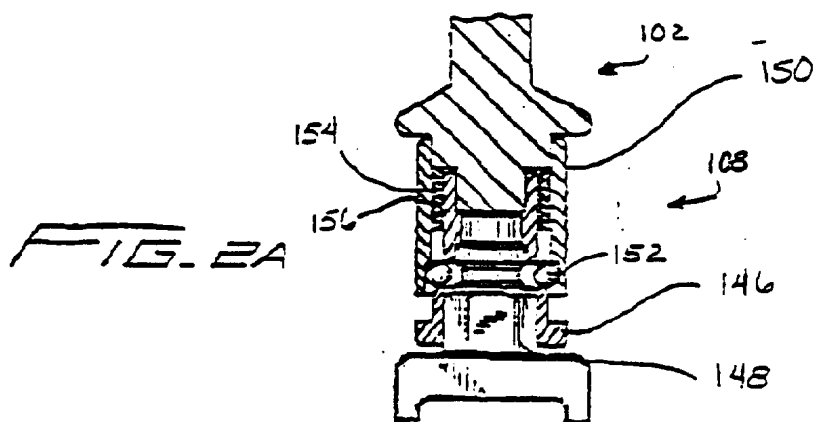


FIG. 2B

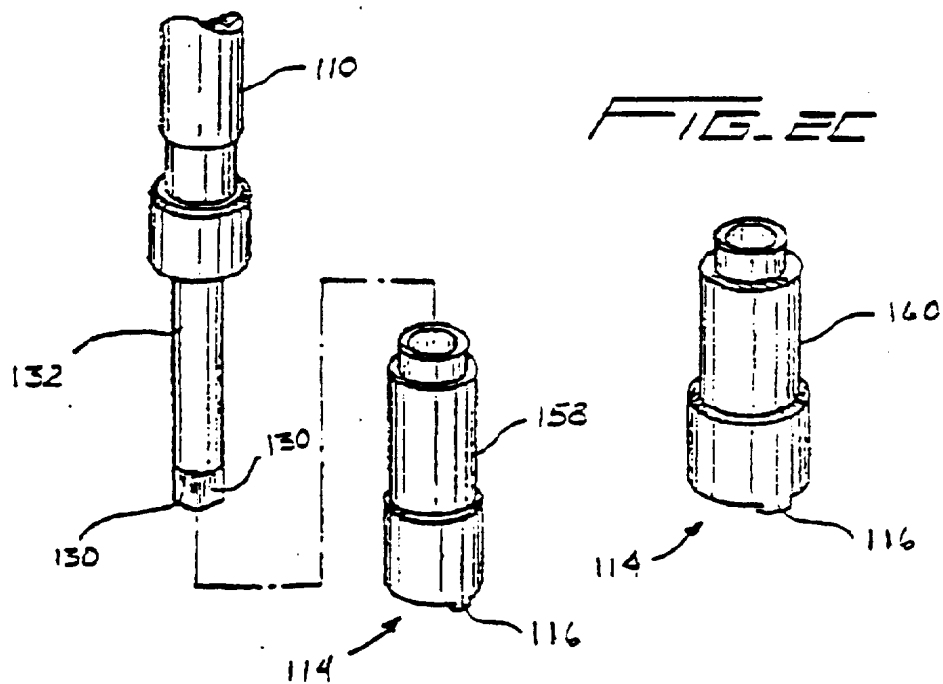


FIG. 2C

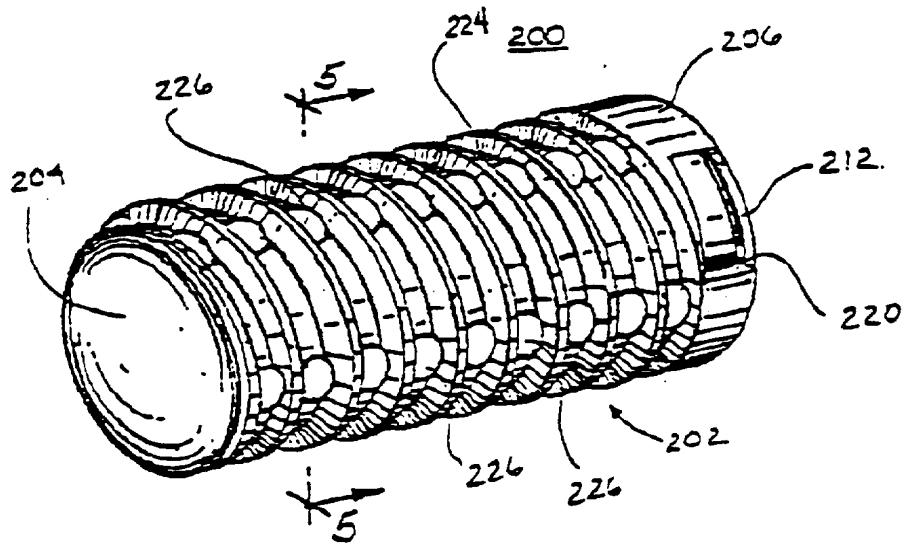


FIG. 3

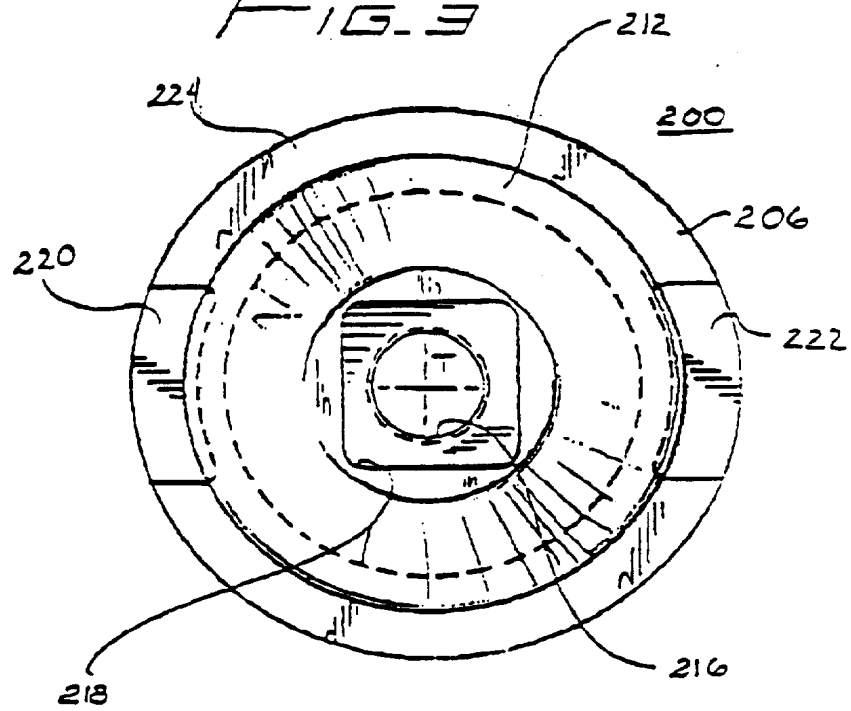


FIG. 4

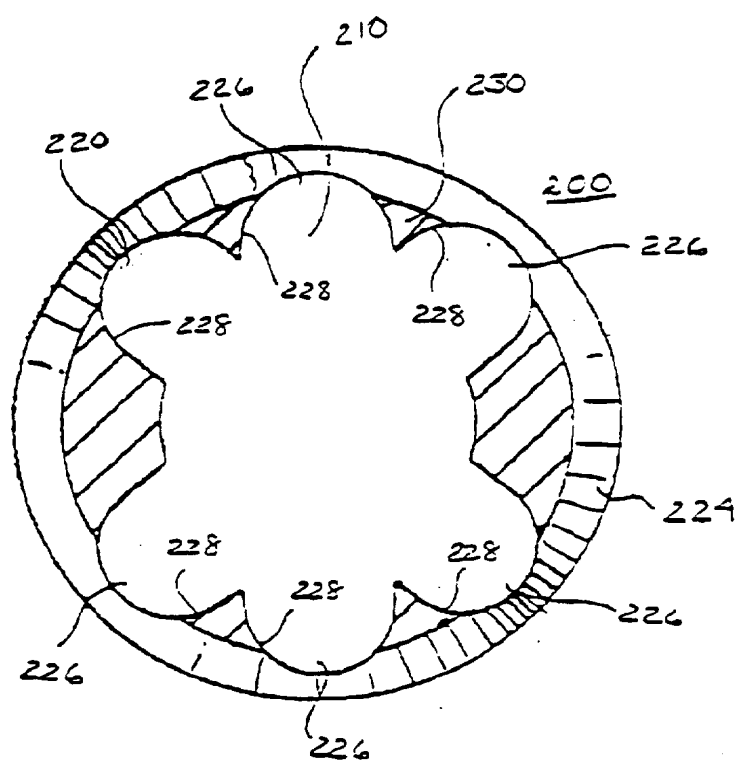
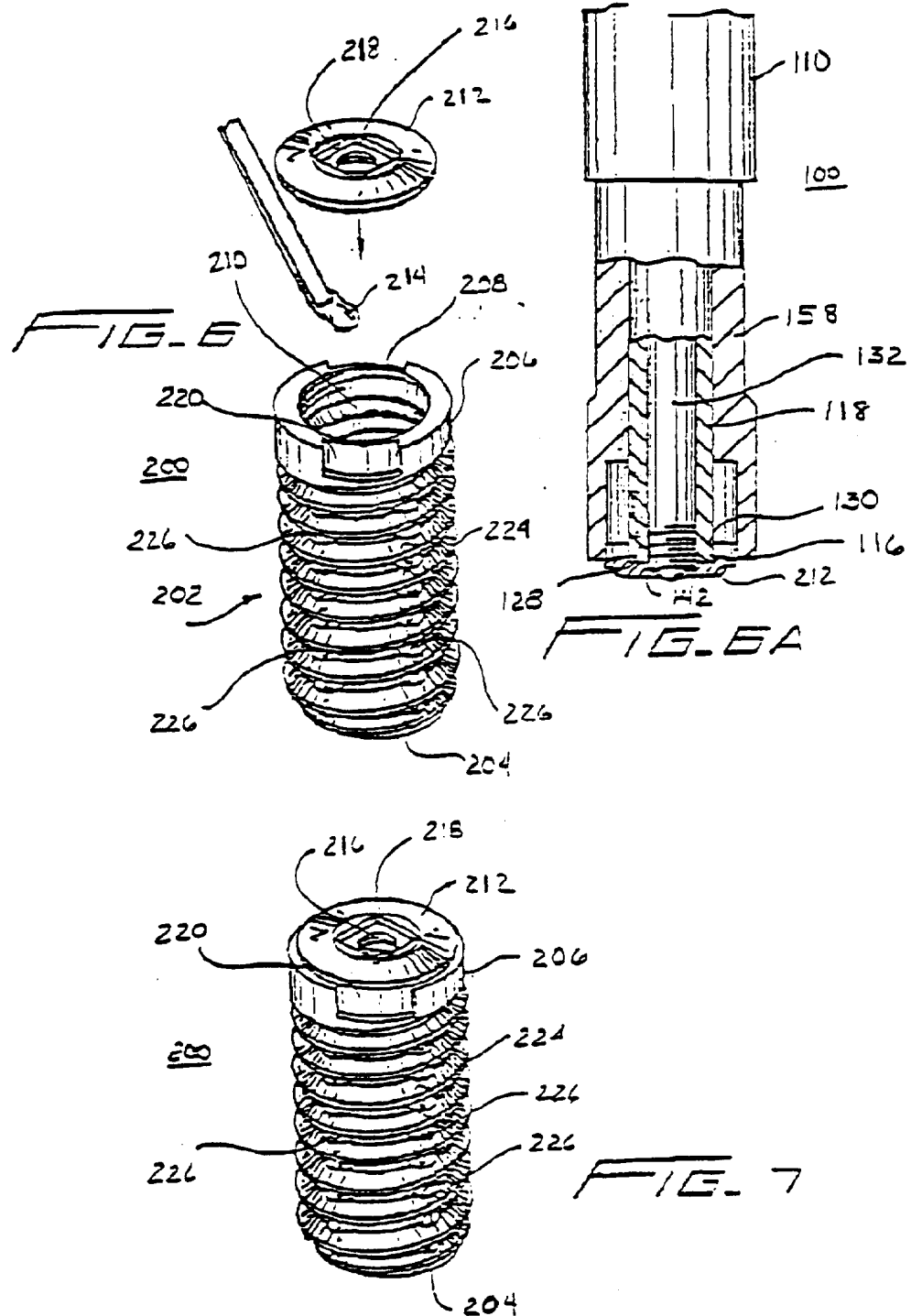
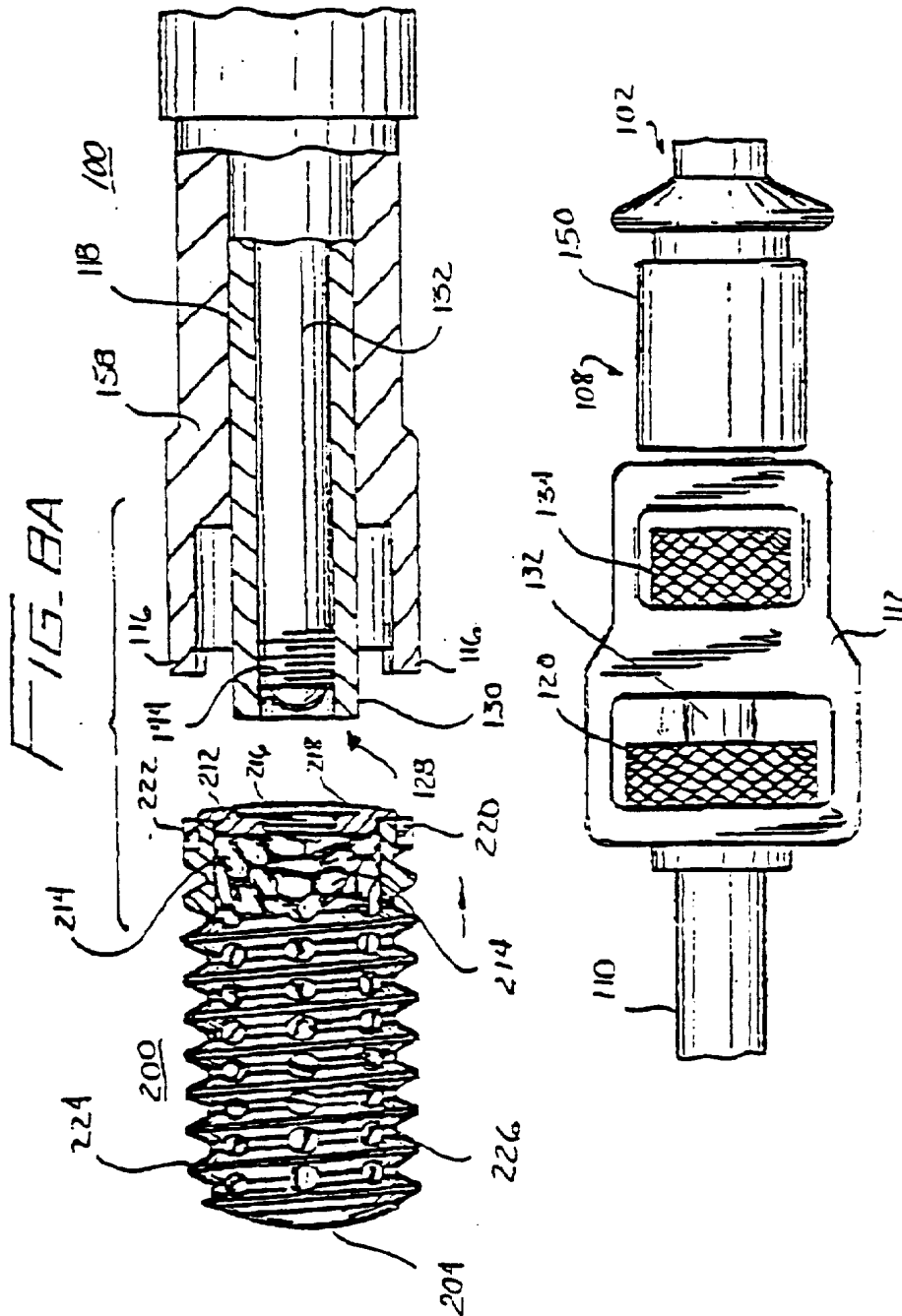
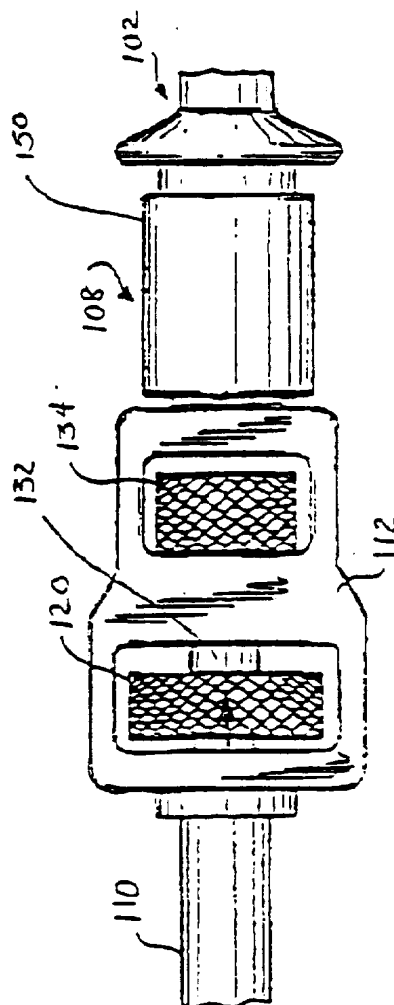
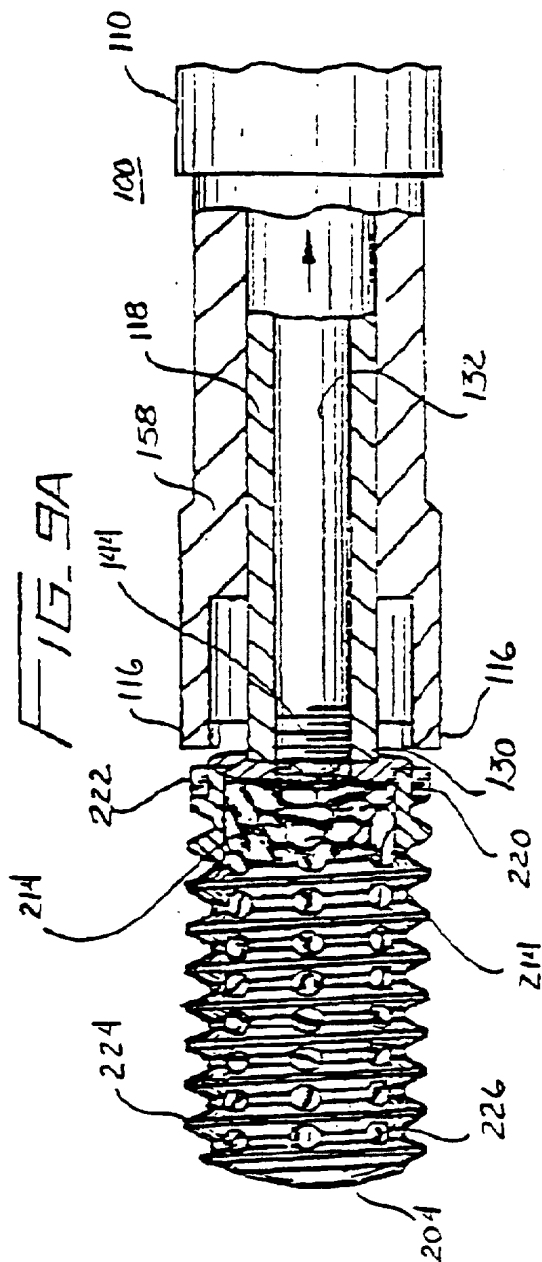


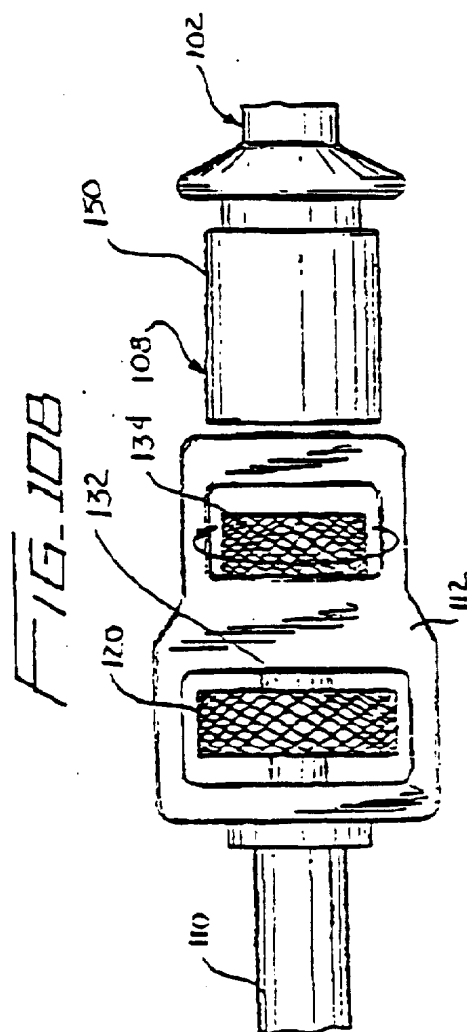
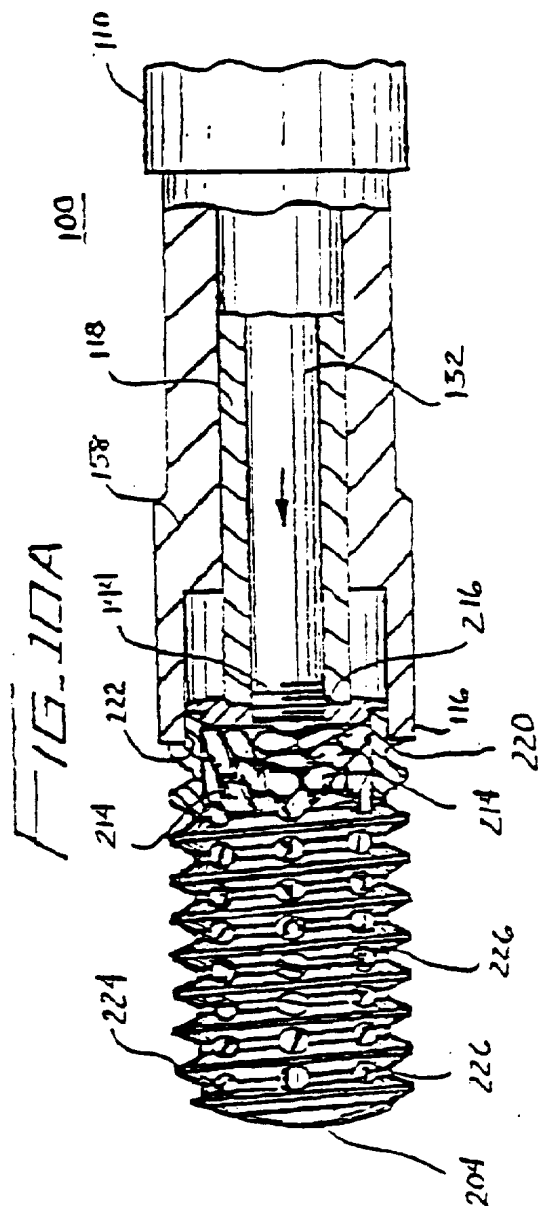
FIG. 5

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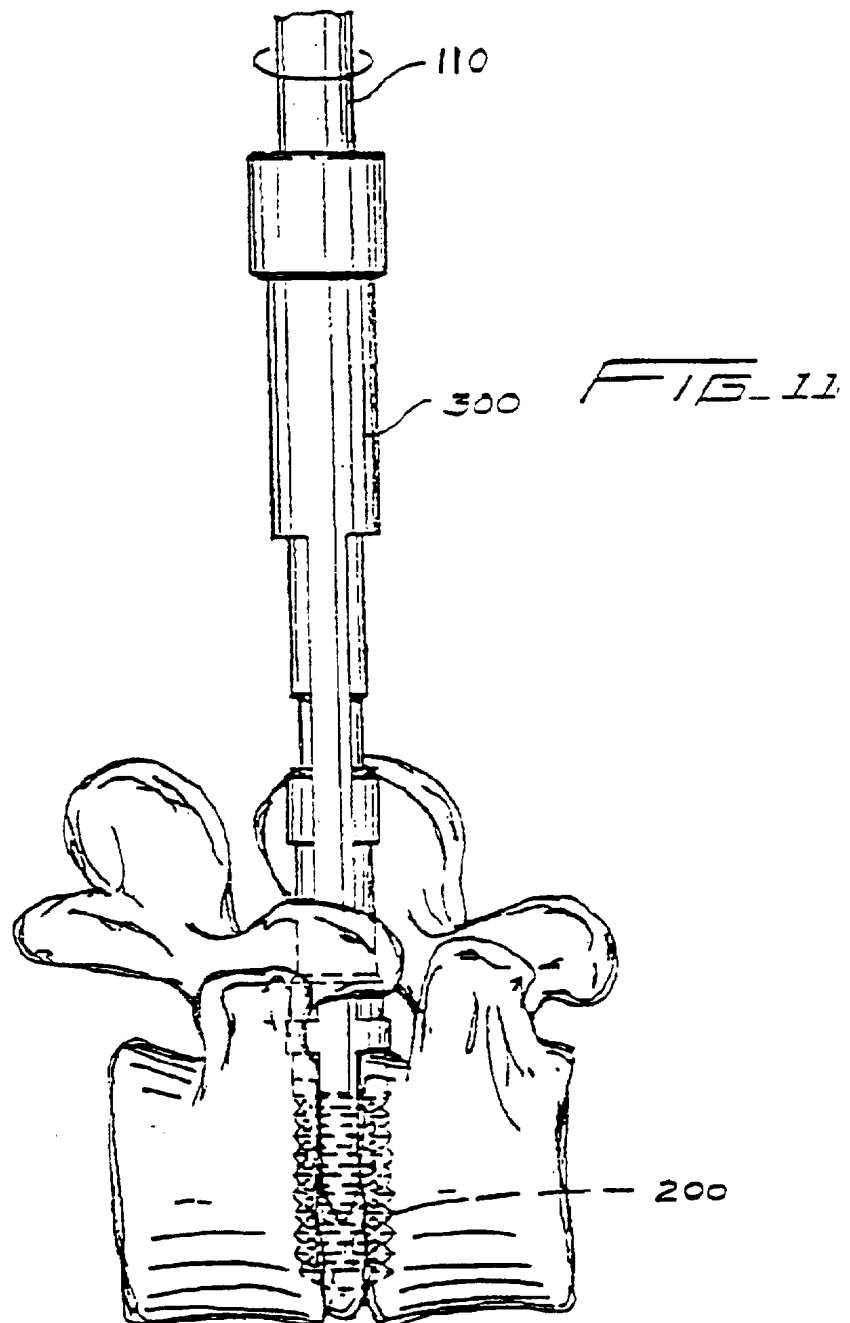
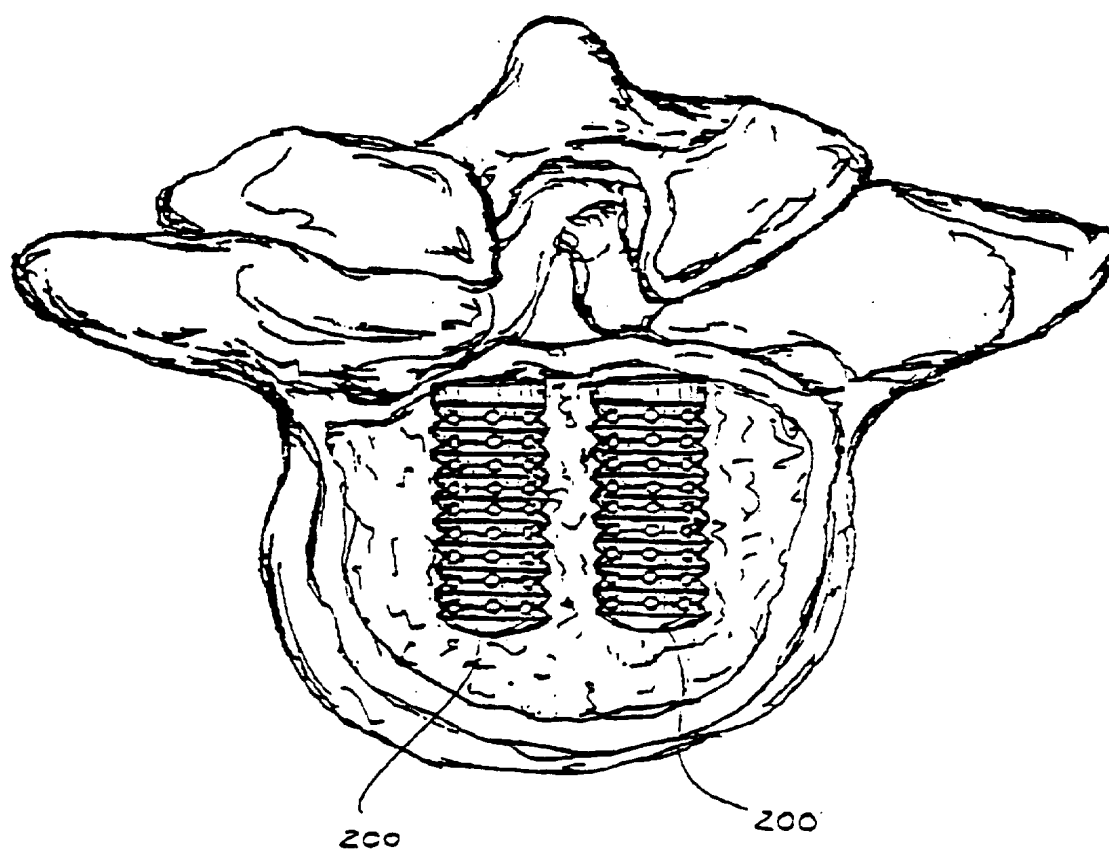


FIG. 12



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/03869

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/56

US CL : 606/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 72, 73, 86, 91, 99, 104; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,489,307 (KUSLICH et al) 06 February 1996, Fig. 56.	1, 3, 4, 7, 9, 10, 13, 15, 17, 19, 20, 25, 26 ----- 2, 8, 14, 18
A	US, A, 5,354,292 (BRAEUER et al) 11 October 1994, Fig. 1A.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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(21) International Application Number: PCT/US90/05318 (22) International Filing Date: 18 September 1990 (18.09.90) (30) Priority data: 432,088 6 November 1989 (06.11.89) US (71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 1240 South Loop Road, Alameda, CA 94501 (US). (72) Inventors: RAY, Charles, D. ; 19550 Cedarhurst, Wayzata, MN 55391 (US). DICKHUDDT, Eugene, A. ; 801 Con- tinental, New Brighton, MN 55112 (US). (74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer & Lovejoy, Four Embarcadero Center, Suite 400, San Fran- cisco, CA 94111-4156 (US).		(81) Designated States: AT (European patent), AU, BE (Euro- pean patent), CA, CH (European patent), DE (Euro- pean patent)*, DK (European patent), ES (European pa- tent), FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>
(54) Title: SURGICAL METHOD AND APPARATUS FOR FUSING ADJACENT BONE STRUCTURES <div data-bbox="422 1176 1218 1575" data-label="Image"> </div>		
(57) Abstract <p>A fusion cage (10) having an external thread (12) can be surgically inserted into a threaded bore extending laterally between the adjacent bony structures such as two vertebrae (94, 95) with the thread (12) penetrating into cancellous bone of each of the vertebrae (94, 95). The fusion cage (10) is easily screwed into place by hand without damage to the bony structures (94, 95). Cage (10) is then packed with a bone-growth-inducing substance such as cancellous bone. When a pair of such cages (10) are implanted between adjacent vertebrae (94, 95), patients have been able to sit without pain by the second or third day, much earlier than has been possible in prior spinal fusions except those involving steel plates and screws. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread (12) of the fusion cage (10) forms a permanent interconnection between the two bony structures (94, 95).</p>		

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SURGICAL METHOD AND APPARATUS FOR FUSING
ADJACENT BONE STRUCTURES

5

CROSS-REFERENCE TO RELATED APPLICATION

10 This is a division and continuation-in-part
of our copending application S.N. 07/259,031, filed
October 17, 1988.

BACKGROUND OF THE INVENTION

Field of the Invention

15 The invention concerns method and apparatus
for fusing two adjacent bony structures such as a bone
joint, especially adjacent vertebrae of the spine.

Description of Related Art

20 Subsequent to injury, diseases or other
degenerative disorder, the disc, a ligamentous cushion
between vertebrae, may undergo a painful
deterioration. The disc shrinks and flattens out, and
the distance between the vertebral bodies begins to
25 collapse. Subsequently, there may be a progressive
degeneration leading to mechanical instability, where
painful translocations occur between adjacent
vertebrae. The movement-induced pain may be so
disabling that in many such cases, the vertebral
30 motion must be eliminated. Thus, rigid fusions may be
the only present means to stop the translocations and
relieve the pain.

35 It is generally held that successful fusions
demand a contiguous growth of bone to create a solid
mass that will unite the movable elements into one
unit. Otherwise, the fusion cannot achieve the tasks

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of pain reduction, maintenance of intervertebral height, and immobility of the vertebrae. When fusion bone is first placed, it is soft and moveable, having no cohesive strength. Therefore a variety of
5 appliances have been developed that attempt to hold the vertebrae quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the vertebrae, the outer or cortical surfaces of which have been removed or deeply
10 scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the vertebrae. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

15 Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue.
20 Such failure is seen in fractures, erosion and absorption of bone with potential further collapse. The pain may also become progressively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by
25 the American Hospital Association. There are many methods for intervertebral fusion. The most successful have achieved a success rate of about 90% in random cases. However, several of these techniques, especially those requiring complex
30 appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

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From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space.

5 Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior
10 surgical approaches are used for interbody fusions. Typically, a plug, dowel or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process,
15 connective tissue and discal tissue must be removed. Deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone
20 grafts have been reported in the orthopedic and neurosurgical literature for some years. B.R. Wiltberger in a paper published in Clinical Orthopedics, Vol 35, pp 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior
25 bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due
30 to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might

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loosen, with a renewed danger of expulsion. See also a 2-page brochure from Neurological Survey Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure:

"is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate bone-to-bone fusion.... The implanted structure is in the form of a perforated cylindrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it.

"The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated

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cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments" (col. 2, lines 26-55).

U.S. Pat. No. 2,537,070 (Longfellow) shows in Fig. 2 a "reinforce 7" that is much like Bagby's fusion basket.

Vich, J. Neurosurg., Vol 63, pp 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft.

"Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertical cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose" (p. 750).

Vich's Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

Vich also says:

"When grafts with a diameter of 14 mm were used, we sometimes threaded the receiving bed with a die-stock of 13 mm to facilitate the insertion" (p. 751).

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An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or appliance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to the vertebrae, such as, dorsal spinous processes or laminae. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower at its most posterior portion. Ventral to this cavity, the stout ligamentous disc annulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

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In U.S. Pat. No. 4,743,256 (Brantigan) pairs of plugs are implanted as struts spanning and maintaining the disc space between adjacent vertebrae. While bone plugs were previously used in the same way, Brantigan employs "rigid plugs of structural material having porous surfaces to facilitate ingrowth of bone tissue" (col. 2, lines 66-68), inserting these into "grooves bridging the cancellous bone of one vertebral body to the cancellous bone of the subjacent vertebral body ..." (col. 2, lines 1-6). "The plugs are preferably made of an inert metal substrate such as stainless steel ... having a porous coating of metal particles ..." (col. 3, lines 8-14). The plug of Fig. 12 "has bone piercing tangs or points 31" (col. 5, line 61).

SUMMARY OF THE INVENTION

The present invention provides a method for implanting a fusion cage in order to fuse adjacent bony structures, which method is safer, surer, easier and faster as compared to the implantation of bone dowels or Brantigan's rigid plug or Bagby's fusion basket or Longfellow's "reinforce." Briefly, the novel implantation method involves the following steps:

- (a) forming between said bony structures a lateral bore with a female thread that penetrates into their cancellous regions,
- (b) forming a hollow cylindrical fusion cage to have an external, substantially continuous helical thread (preferably a V-thread) that is

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perforated in the valley between adjacent turns
and can mate with said female thread,

(c) screwing the cage into said thread bore,
and

5 (d) packing the cage with bone-inducing
substance.

The female thread formed in step (a)
preferably is tapped by hand, using a slow motion to
ensure against burning the bone. This freshens the
10 bone margins of the bore so that if any bone had been
burned by drilling to form the bore, it is now cut
away slowly by hand. The tapping process is quite
safe, in that the surgeon can feel the progress of the
technique.

15 The V-thread or other male-thread fusion cage
preferably is screwed by hand into the threaded bore,
again permitting the surgeon to feel if the resistance
is too great and that rethreading of the bore might be
required. In contrast, a bone dowel typically is
20 driven into a bore using a hammer, and in order to
guard against an overly tight fit, the surgeon listens
to the sound of the striking hammer and also monitors
the degree of resistance.

Parent U.S. patent application S.N.
25 07/259,031 indicates that the V-thread fusion cage
preferably is made of implantable-grade stainless
steel and that titanium is also useful. Currently,
titanium is preferred, it having been shown to be more
compatible to bone.

30 Parent U.S. patent application S.N.
07/259,031 also teaches that the V-thread fusion cage
preferably is fitted with end caps. The end caps

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preferably are X-ray transparent to permit post-operative checks on the status of the developing bone. X-ray transparent end caps can be stamped from a flexible sheet of thermoplastic resin such as "Delrin" acetal resin or polypropylene and may have a small opening for an instrument by which they can be put into place.

5
10 A threaded bore into which a hollow cylindrical fusion cage can be surgically implanted to fuse adjacent bony structures can be prepared by the steps of:

- (a) drilling a pilot hole laterally between said bone structures,
- 15 (b) inserting a pilot rod into the pilot hole,
- (c) fitting a hollow drill over the pilot rod,
- (d) with the hollow drill, enlarging the pilot hole to form a bore that penetrates into the cortical bone of each of said bony structures, and
- 20 (e) tapping a female thread into the wall of said bore with the crown of the thread penetrating into the cancellous portion of each of said bony structures.

25 When using a male-thread fusion cage between adjacent vertebrae to promote bone ingrowth, the fusion cage should be implanted in pairs on opposite sides of the disc space. After placement of the first cage, there is an impressive, instant stabilization of the previously unstable vertebral segment. The second

30 cage is then screwed into its tapped hole, thus rendering the space completely immobile. Each cage is

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held in place by its male-thread, biting into female threads that were formed in step (e). Gravity, muscle pull and elastic recoil of the spread (or stretched) outer disc annulus together exert force against each of the fusion cages. Thus the fusion cages are held in place by compression forces between the adjacent vertebrae.

Because the cancellous bone of the vertebral bodies has internal strength similar to wet balsa wood and a hard shell similar to about a 1.5 mm veneer of white oak, it is difficult to drill parallel bores without the drill bits wandering into a common center, unless a drill guide or jig is provided. This problem is met by the following method of forming and threading a bore between adjacent vertebrae, which method involves the following steps:

- (a) cutting away ligaments to expose the site,
- (b) spreading the vertebrae apart,
- (c) nibbling away as much of each lamina as is necessary to access the site,
- (d) drilling a pilot hole laterally between said vertebrae, each of sufficiently small diameter to be self-seeking of the center of the disc space,
- (e) inserting a pilot rod into the pilot hole,
- (f) sliding over the pilot rod a hollow lamina drill to cut the spinous process and to score the lamina,
- (g) drilling to remove the lamina within the score,

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(h) fitting into the resulting arcuate opening in the lamina a C-retractor which has a split cylindrical sleeve of the same diameter as the lamina drill, a handle extending from one end toward the upper end of the spine, and spikes at its outer end,

(i) forcing at least one of the spikes into each of said adjacent vertebrae to anchor the C-retractor,

(j) reinserting the pilot rod to rest on the bottom of the pilot hole,

(k) sliding a hollow vertebral drill over the pilot rod and inside the sleeve of the C-retractor,

(l) forming with the hollow drill a bore that penetrates into the cortical bone of each of said vertebrae,

(m) removing the hollow drill, the pilot rod, and the cut bone, and

(n) using the C-retractor as a guide, tapping a female thread, the crown of which extends into the cancellous bone of each of the vertebrae.

As indicated in the drawing, said pilot rod and the shafts of said hollow lamina drill and tap having markings to show the depths to which they penetrate into the bore.

When male-thread fusion cages are to be positioned between adjacent vertebrae, the sides that are to face laterally preferably are closed to prevent disc tissue from growing into the cages, because this could interfere with bone growth between the

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vertebrae. By leaving the lateral sides closed, the fusion cages have greater structural strength, thus permitting the perforations adjacent the vertebrae to be larger. When leaving the lateral quadrants closed, we have achieved 70% perforation of the area of the top and bottom quadrants (as projected onto the inner face of a cylinder) while maintaining good compressive strength.

End caps can help to prevent disc tissue from growing into the cages, and for this reason, any openings in the end caps should be small.

A large majority of patients requiring intervertebral fusions have narrowing of the disc space, typically 10 mm or less in the lower back. Because minimal penetration into the end plates of the vertebrae is required (about 3mm for each), three major diameters of the fusion cage thread should suffice for most patients, namely, 14, 16 and 18 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion cage preferably does not exceed 25 mm but is at least 20 mm in length to give sufficient contact as well as a good platform when implanted in pairs.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument.

Other instruments that have been developed for use in the implantation of the novel fusion cage include tapping instruments for forming helical

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threads in a bore in recipient bone. A first novel tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slideably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using this first novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three, because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

Said first novel tapping instrument and a novel wrench are illustrated in the drawing, together with other instruments that can be used to implant male-thread fusion cages surgically.

THE DRAWINGS

In the drawing, all figures of which are schematic,

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Fig. 1 is an exploded isometric view of a first V-thread fusion cage of the parent U.S. Patent Application S.N. 07/259,031 and two perforated end caps;

5 Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion cages of said U.S. Patent Application S.N. 07/259,031;

10 Fig. 3 is an isometric view of a first tapping instrument (partly cut away to reveal details of construction) for forming female threads in bores into which male-thread fusion cage is to be inserted;

15 Fig. 4 is an isometric view of a wrench for screwing a male-thread fusion cage into a threaded bore;

Fig. 5 is an exploded isometric view of a third male-thread fusion cage of said U.S. Patent Application S.N. 07/259,031;

20 Fig. 6 is a plan view of a pilot drill that can be used in preparation for forming a threaded bore laterally between two vertebrae into which a male-thread fusion cage can be surgically implanted;

Fig. 7 is a plan view of a pilot rod that also can be used in preparation for forming said threaded bore;

25 Fig. 8 is a plan view of a hollow lamina drill that can be used in conjunction with the pilot rod of Fig. 7;

30 Fig. 9 is an isometric view showing the use of a C-retractor in preparation for the surgical implantation of a pair of male-thread fusion cages between two vertebrae;

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Fig. 10 is a plan view of a hollow vertebral drill that also can be used with the pilot rod of Fig. 7; and

5 Fig. 11 is a plan view of a second tapping instrument that can be used in conjunction with the C-retractor of Fig. 9 to tap a female thread in the bore formed by the hollow vertebral drill of Fig. 10.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

10 The fusion cage 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled
15 centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14
20 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion cage to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps
25 would also be useful.

In making a fusion cage by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole.
30 Enlarged small holes would result in larger perforations 13.

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Referring to Fig. 2, a series of fusion cages can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion cages each of which has perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion cage identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion cages in Figs. 1 and 2 could be made from a model by the lost wax process.

The tapping instrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end. Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown)

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to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads.

5 Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry
10 detritus upwardly to be deposited through the scallops into the reservoir.

 Upon rotating the hollow shaft 31 to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes
15 full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to
20 be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

25 The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion cage to permit the fusion cage to be
30 rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion cage.

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Fig. 5 shows a third male-thread fusion cage 50 that has formed from a solid steel cylinder by drilling an axial bore 51 and then broaching out a pair of cylindrical channels 52 that extend to a diameter only a little smaller than the external surface of said cylinder. A V-thread 53 has then been machined in that external surface, thus creating perforations 54 in the valley between adjacent turns of the thread, each perforation extending completely across one of the channels 52. Each end of each land between the channels has been machined to have a recess 56 to enable an end cap 57 to fit flush with the end of the fusion cage. At each recess 56, each land has been formed with a small bore 58 into which one of a pair of projections 59 from the end cap 57 fits snugly to hold the end cap in place.

In Fig. 6, a pilot drill 60 has a T-handle 62 at one end of a shaft 63 and at the other end a collar 64 holding a bit 66. A set screw 68 in the collar permits the protruding length of the bit to be adjusted, and the larger diameter of the collar acts as a stop. Typically, the bit 66 extends 25 mm beyond the collar 64.

In Fig. 7, a pilot rod 70 has a cylindrical shaft 71, at one end of which is a cylindrical boss 72 that is 30 mm in length and slidably fits into a bore formed by the pilot drill 110 of Fig. 11. The boss 72 has two scribe marks 73 that indicate the depth in cm of the bore. At its other end, the shaft 71 is formed with a flat 75 that has scribe marks 76 marked to indicate 0, 1, 2 and 3 cm for purposes explained below.

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Shown in Fig. 8 is a hollow lamina drill 80 which has a cutting edge 82 and a central bore 83 that slidably fits over the shaft 71 of the pilot rod 70. An anodized aluminum handle 84 permits a surgeon to

5 drive the lamina drill by hand.

Shown in Fig. 9 is a C-retractor 90 which has a cylindrical sleeve 91 that is formed with an opening 92 across about one-fourth of its circumference over its full length. Extending from one end of the sleeve

10 opposite to said opening 92 is a malleable handle 93 by which the cylindrical sleeve 91 can be fitted through the arcuate laminotomy (formed by the lamina drill 80) down to the vertebrae 94 and 95. At the

15 other end of the sleeve 91 are four spikes 96 in two pairs, one pair on either side of a line that is 180° from the center of said opening 92. When the sleeve of the C-retractor 90 is concentric with a pilot bore that has been drilled laterally into the disc 97

20 between the two vertebrae 94 and 95, one pair of the spikes can be set into the dorsal surfaces of each vertebra after careful orientation to be concentric with the pilot rod 70 while it is seated in the pilot bore. As also shown in Fig. 9, one purpose of the sleeve 91 of the C-retractor 90 is to keep tools from

25 contacting the dura 98 and the spinal nerve 99.

Shown in Fig. 10 is a hollow vertebral drill 100, the shaft 101 of which is formed with a central bore (not shown) that slidably fits over the shaft 71 of the pilot rod 70 while the C-retractor 90 is in

30 place. At one end of the hollow drill are scalloped cutting edges 105, and at the other is a hard rubber handle 103 that permits a surgeon to drive the

- 20 -

vertebral drill by hand. Scribe marks 107 indicate 0, 1, 2 and 3 cm. The 0 mark is at the top of the cylindrical sleeve 91 of the C-retractor when the vertebral drill is first put into place, and it and the other marks sequentially disappear behind the cylindrical sleeve as the vertebral drilling progresses. At the same time the scribe marks 76 on the flat 75 of the shaft 71 of the pilot rod 70, appear behind the handle 103 of the vertebral drill. While the surgeon watches the disappearance of the scribe marks 107 on the vertebral drill, a surgical assistant holds the pilot rod at the proper attitude and monitors the progress of the drilling by watching the appearance of the scribe marks 76 on the pilot rod. The greater inside diameter of the C-retractor 90 compared to that of the scalloped cutting edges 105 affords to the surgeon the opportunity to make slight lateral corrections as the drilling progresses.

Shown in Fig. 11 is a second tapping instrument 110, the tap 112 of which slidably fits into the cylindrical sleeve 91 of the C-retractor 90. At the other end of its shaft 113 is a T-handle 114 by which a surgeon drives the tap until it reaches the depth of the bore.

Implanting the Fusion Cage of Fig. 1

In order to implant the fusion cage 10 between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminae of each side, namely standard laminotomies. The neural tissues, dural sac and nerves, are

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retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x-ray. The height of the disc space is measured on the x-ray so that the proper sizes of drills, tap, and fusion cage may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about 25 mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion cage of the invention with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the

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threaded intradiscal bore to its full depth. After removing the wrench, the cage is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion cage by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion cages and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion cages will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the vertical spine.

Example 1

The fusion cage of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

diameter of starting cylinder	16 mm
length of cylinder	25 mm
diameter of each small hole 11	3 mm
diameter of circle on which	
holes 11 are centered	11.5 mm
diameter of central hole	11 mm
pitch of V-thread 12	2.5 mm/turn

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	angle at crown of thread 12	60°
	fillet radius in valley of	
	thread 12	0.4 mm
	axial width of perforation 13	1.6 mm
5	circumferential breadth of	
	perfs. 13	2.8 mm
	when projected onto interior	
	of a cylinder, % of area	
	perforated	25%

10

Example 2

The fusion cage of Fig. 1 has been machined from a stainless-steel cylinder to have the same dimensions as that of Example 1 except that the diameter of the circle on which holes 11 were centered was increased to 12 mm. This results in 70% perforation in each of the areas of the top and bottom quadrants.

To test the compressive strength, a pine block was drilled to the outside diameter of the thread of the fusion cage, and a 1/4-inch section was cut away to leave two pieces, between which the fusion cage was placed with its perforations facing two pieces. A force of 808 pounds was applied before the fusion cage began to deform into an oval shape, thus indicating that it has much more than adequate compressive strength to withstand any forces to which it might be put when implanted between a person's vertebrae.

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Example 3

A fusion cage, identical to that of Example 2 except that the cage was made from titanium, was tested in the same way for compressive strength. It resisted 850 pounds before beginning to deform.

Surgical Experience

The fusion cage of Example 2 has been surgically implanted in pairs between adjacent vertebrae of each of three persons. In each case after placement of the first cage, there was an impressive, instant stabilization of the previously unstable vertebral segment. Upon threading the second cage into its tapped hole, the segment became completely immobile.

Each of those three patients was able to tolerate sitting without low back pain by the second or third post-surgical day. This unexpectedly early comfort expressed by each of these three patients signified good, immediate stability to the previously painfully unstable spinal segment.

The first patient, on a routine visit at two months postoperative, had an almost full range of painless motion (bending, twisting) of the lumbar spine. The second patient, at 18 days postoperative, made an unscheduled visit to ask permission to go biking and reported a greater than 90% relief of all back and leg pains. The third patient showed approximately 1/3 range of normal painless motion of the lumbar spine on the sixth postoperative day.

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What is claimed is:

1. Surgical method of fusing adjacent bony structures, said method comprising the steps of:

5 (a) forming between said bony structures a lateral bore with a female thread that penetrates into their cancellous regions,

(b) forming a hollow cylindrical fusion cage to have an external, substantially continuous helical
10 thread that is perforated in the valley between adjacent turns and can mate with said female thread,

(c) screwing the cage into said threaded bore, and —

(d) packing the cage with bone-inducing
15 substance.

2. Method as defined in claim 1 wherein said threaded bore extends into the disc space between adjacent vertebrae, and prior to step (a) is the added
20 step of spreading said vertebrae apart.

3. Method as defined in claim 2 wherein a second threaded bore is formed to extend into the opposite side of said disc space and parallel to said
25 threaded bore, and steps (b), (c) and (d) are repeated to implant an identical fusion cage in said second threaded bore.

4. Method as defined in claim 1 wherein
30 said female thread is formed in step (a) by hand tapping.

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5. Method for surgically preparing two adjacent bony structures for implanting a hollow cylindrical fusion cage that has an external, substantially continuous helical thread and is perforated in the valley between adjacent turns of the thread, said method comprising the steps of:

- (a) drilling a pilot hole laterally between said bony structures,
- (b) inserting a pilot rod into the pilot hold,
- (c) fitting a hollow drill over the pilot rod,
- (d) —with the hollow drill, enlarging said pilot hole to form a bore that penetrates into the cortical bone of each of said bony structures, and
- (e) tapping a female thread into the wall of said bore, the crown of which penetrates into the cancellous portion of each of said bony structures, which female thread can mate with the helical thread of the fusion cage.

6. Method as defined in claim 5 wherein said bore extends laterally into the disc space between adjacent vertebrae.

7. Method as defined in claim 6 wherein steps (a) through (e) are repeated to form a second threaded bore parallel to the first, one on each side of the disc space.

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8. Method as defined in claim 7 wherein each said female thread is formed in step (e) by hand tapping.

5 9. Method as defined in claim 5 and further comprising subsequent to step (e) the steps of:

 (f) screwing the fusion cage into said threaded bore, and

 (g) then filling the cage with bone-inducing
10 substance.

10. Method as defined in claim 9 wherein the bone-inducing substance is cancellous bone chips.

15 11. Method for surgically preparing two adjacent vertebrae for implanting a hollow cylindrical fusion cage that has an external, substantially continuous helical thread and is perforated in the valley between adjacent turns of the thread, said
20 method comprising the steps of:

 (a) cutting away ligaments to expose the site,

 (b) spreading the vertebrae apart,

 (c) nibbling away as much of the lamina as
25 is necessary to access the site,

 (d) drilling a pilot hole laterally between said vertebrae, each of sufficiently small diameter to be self-seeking of the center of the disc space,

 (e) inserting a pilot rod into the pilot
30 hole,

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(f) sliding over the pilot rod a hollow lamina drill to cut the spinous process and to score the lamina,

5 (g) drilling to remove the lamina within the score,

(h) fitting into the resulting arcuate opening in the lamina a C-retractor which has a split cylindrical sleeve of the same diameter as the lamina drill and a handle extending from one end toward the upper end of the spine,

10 (i) reinserting the pilot rod to reset on the bottom of the pilot hole,

(j) sliding a hollow vertebral drill over the pilot rod and inside the sleeve of the C-retractor.

15 (k) forming with the hollow drill a bore that penetrates into the cortical bone of each of said vertebrae,

(l) removing the hollow drill, the pilot rod, and the cut bone, and

20 (m) using the C-retractor as a guide, tapping a female thread, the crown of which extends into the cancellous bone of each of the vertebrae.

25 12. Method as defined in claim 11 and comprising the added step of maneuvering aside the dura and nerve with said split cylindrical sleeve of the C-retractor.

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13. Method as defined in claim 12 wherein
the C-retractor is formed with spikes extending
axially from one end of said cylindrical sleeve, said
method comprising the added step of forcing at least
5 one of said spikes into each of said adjacent
vertebrae to anchor the C-retractor.

14. A tapping instrument for forming a
female thread in a bore into bone, said tapping
10 instrument comprising:

a hollow cylindrical shaft having a handle at
one end and an external thread which is formed at the
other end with at least one scallop that exposes a
cutting edge at the leading edge of the external
15 thread so that a female thread is formed in said bore
upon rotation of the hollow shaft,

a pilot rod that slidably fits into said
bore, projects beyond said other end of the hollow
shaft, and is formed with a central recess that
20 communicates with said scallop and provides a
reservoir for detritus removed by said cutting edge,
thus permitting the detritus to be carried away by
removing the pilot rod from the hollow shaft.

25 15. A tapping instrument as defined in claim
14 and symmetrically formed with three scallops and
cutting edges.

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16. A tapping instrument as defined in claim 14 wherein said one end of the pilot rod has external threads which, when the threaded pilot rod is turned, carry detritus to be deposited through the scallops into the reservoir.

17. A C-retractor comprising a cylindrical sleeve that is split to form an opening across a small fraction of its circumference over its full length, a malleable handle extending from one end of the sleeve opposite to said opening, and spikes protruding axially from the other end of the sleeve.

18. A C-retractor as defined in claim 17 and having four of said spikes in two pairs with one pair on either side of a line that is 180° from the center of said opening.

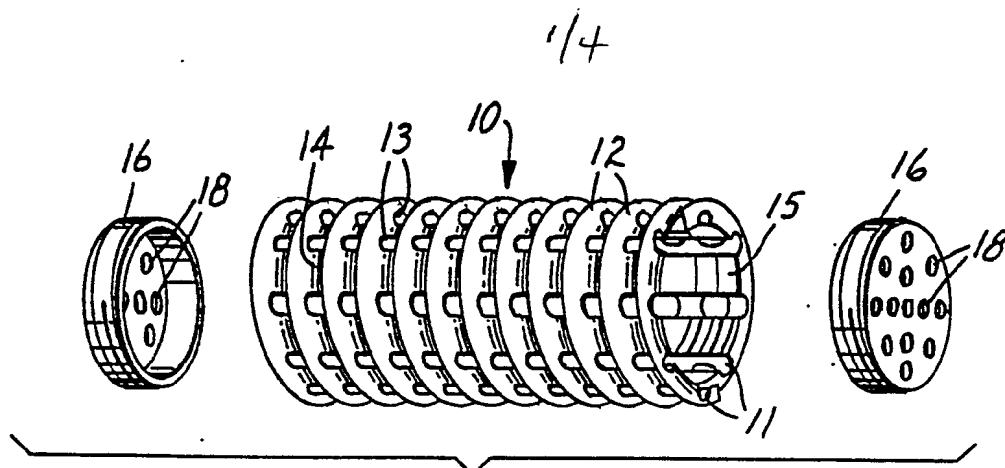


FIG. 1

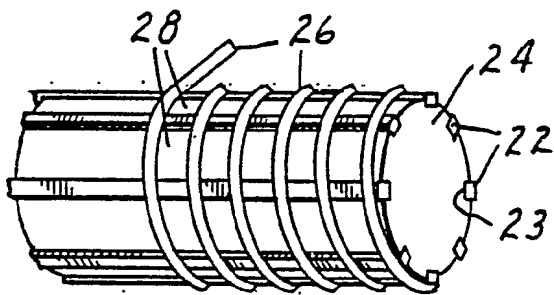


FIG. 2

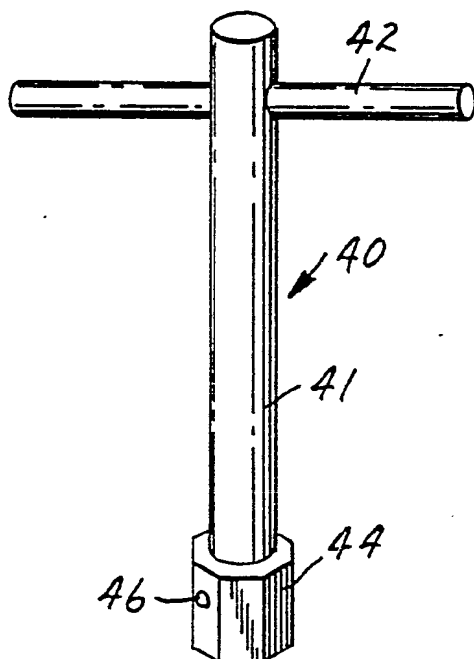


FIG. 4

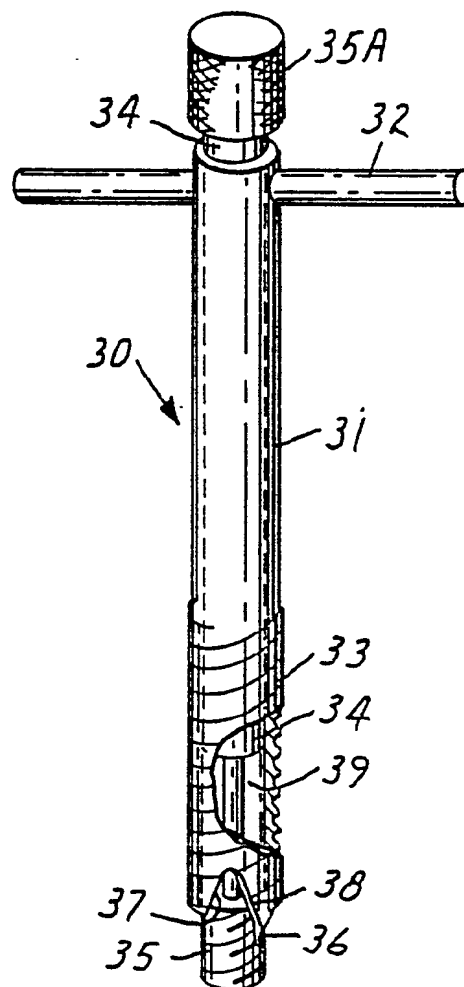
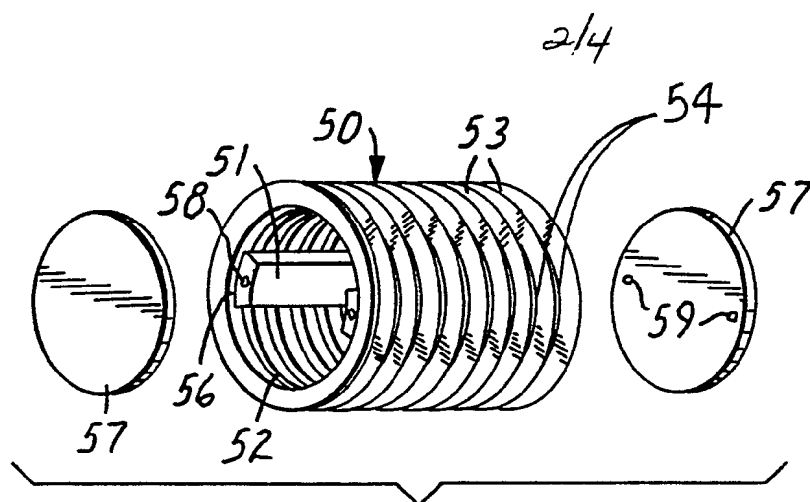
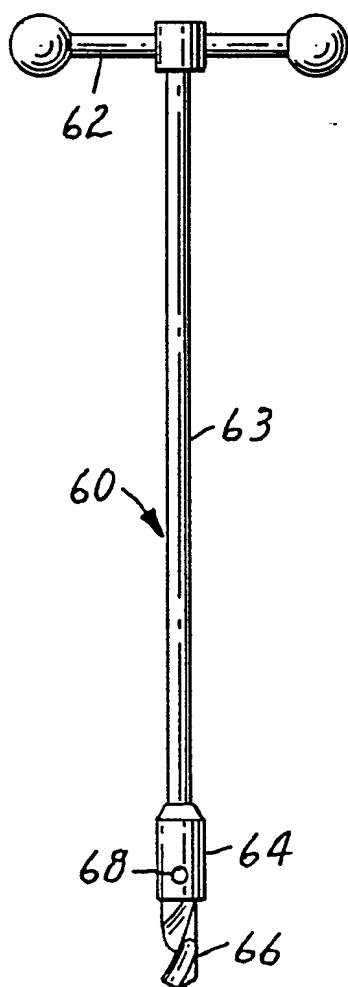
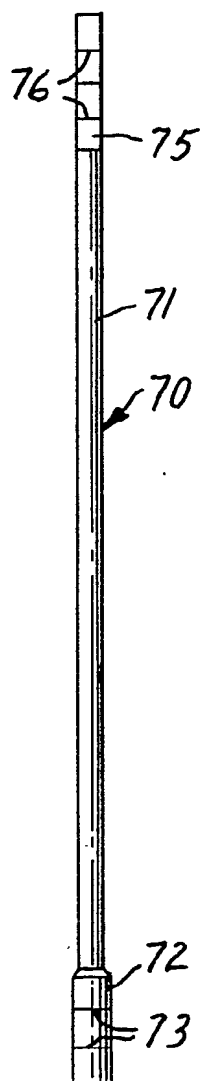
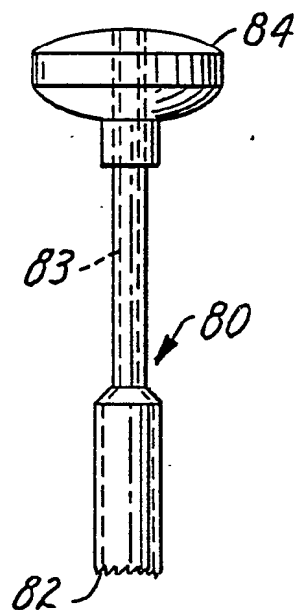
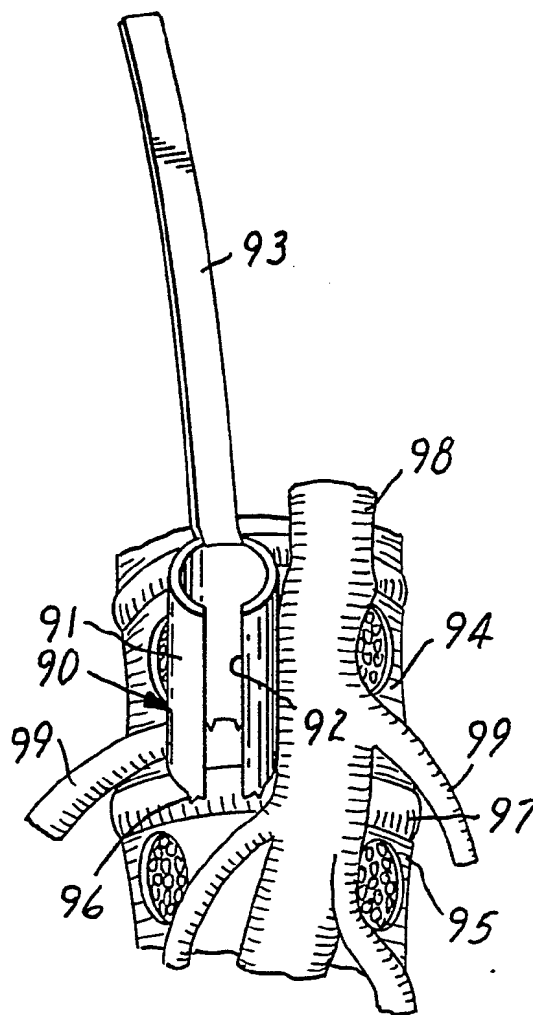


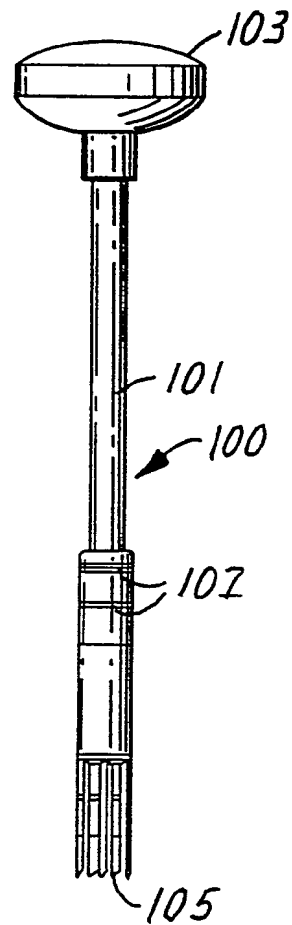
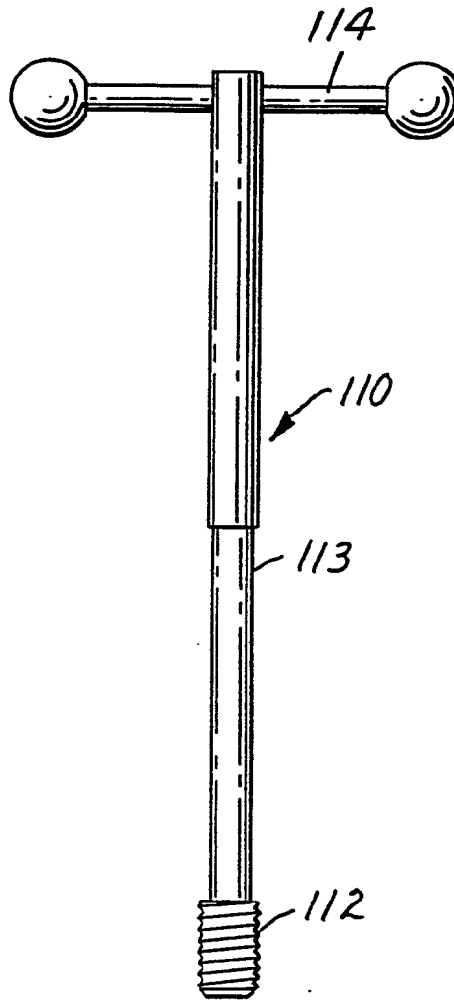
FIG. 3

**FIG. 5****FIG. 6****FIG. 7****FIG. 8**

3/4

*FIG. 9*

4/4

**FIG. 10****FIG. 11**

INTERNATIONAL SEARCH REPORT

International Application No **PCT/US90/05318**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³ According to International Patent Classification (IPC) or to both National Classification and IPC IPC : A61F 2/44 US : 606/61,79,99;623;17						
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ⁴</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px; vertical-align: top;">US</td> <td style="padding: 5px; vertical-align: top;">606/61,86,79,80,81,96,99,108 623/16-22</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵</div>			Classification System	Classification Symbols	US	606/61,86,79,80,81,96,99,108 623/16-22
Classification System	Classification Symbols					
US	606/61,86,79,80,81,96,99,108 623/16-22					
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴						
Category [*]	Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸				
A	US,A RE 31865 (ROUX) 16 April 1985	1-13				
A	US,A 4492226 (BELYKH ET AL) 8 January 1985					
A	US,A 4599086 (DOTY) 8 July 1986					
A	US,A 4522200 (STEDNITZ) 11 June 1985					
A	US,A 4677972 (TORNIER) 7 July 1987	1-13				
A	US,A 3783860 (BURSTEIN ET AL) 8 January 1974					
A	US,A 4059115 (JUMASHEV ET AL) 22 November 1987	14-16				
A	US,A 4657550 (DAHER) 14 April 1987					
A	US,A 4501269 (BAGBY) 26 February 1985					
A	US,A 3848601 (MA ET AL) 19 November 1974					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁶</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"..." document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>document member of the same patent family</p> </div> </div>						
IV. CERTIFICATION						
Date of the Actual Completion of the International Search ² <div style="text-align: center; font-size: 1.2em;">24 January 1991</div>		Date of Mailing of this International Search Report ² <div style="text-align: center; font-size: 1.2em;">08 MAR 1991</div>				
International Searching Authority ¹ <div style="text-align: center; font-size: 1.2em;">ISA/US</div>		Signature of Authorized Officer ²¹ <div style="text-align: center;"> <div style="text-align: center; font-weight: bold;">KERRY OWENS</div> </div>				

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No ¹⁸
A	US, A 3651807 (HUGGINS) 28 March 1972 see figure 1	17,18
A	US, A 4585437 (SIMMS) 29 April 1986 see figure 1	17,18
A,P	US, A 4878915 (BRANTIGAN) 7 November 1989	1-16

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	DE, A 3505567 (VICH) 5 June 1986	
A	FR, A 2295729 (MAHAY + CIE) 23 July 1976	1-13
<u>X</u> Y	US, A 4802468 (DOWLAN) 7 February 1989 see figure 3	<u>14</u> 15
Y	US, A 4649918 (PEGG ET AL) 17 March 1987 see column 2, lines 47-50	15

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter¹ not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out¹, specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.